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Expert Report of Thani Jambulingam, Ph.D.

Nationwide Prescription Opiate Litigation
MDL No. 2804

May 10, 2019

TABLE OF CONTENTS

Page

I. Introduction

I was engaged by counsel at Reed Smith, LLP, to serve as an expert witness in the following matters: In Re National Prescription Opiate Litigation, MDL No. 2804, Case No. 17-md-2804 for the Cuyahoga and Summit County consolidated cases (collectively, "Plaintiffs"). My opinions set forth in this report are based upon my background, training, education, experience, and my review of the professional literature, among other things. A full list of the publications and materials reviewed and considered in preparation of this report and/or cited within this report is attached as **Appendix A**. In addition, my opinions set forth in this report are stated to a reasonable degree of professional certainty. I reserve the right to supplement or amend this report upon review of additional materials or information provided to me by the parties in this case, any other materials or information that may become available, and/or at the request of counsel for additional analyses. I further reserve the right to offer opinions within my area of expertise in response to additional opinions and/or subjects offered or addressed by other experts on behalf of the Plaintiffs.

II. Professional Background and Qualifications

My name is Thanigavelan Jambulingam. I am a Professor at Saint Joseph's University in the Department of Pharmaceutical and Healthcare Marketing, in Erivan K. Haub School of Business. I received my Bachelor of Science in Pharmacy from Madras Medical College in Chennai, India in 1985. In 1986, I obtained my Master's degree in Pharmaceutical Technology with a concentration in Pharmaceutical Chemistry and a minor in pharmacology. In 1994, I obtained a Master's degree in Pharmacy Administration, and in 2001, I receive a Ph.D. in Pharmacy Administration and Business minor in Marketing at University of Wisconsin, Madison, WI. During this time, I was a Research Assistant at the Center for Supply Chain Management in the Business School at UW-Madison. My advisor was Dr. Jack Nevin.

My M.S. thesis is on generic pharmaceutical pricing and titled "Relationship between the Number of Firms and Generic Drug Pricing." My Ph.D. dissertation in the area of supply chain management is "Antecedents and Consequences of Channel Process Integration: An Empirical Investigation in the Pharmaceutical Supplier – Pharmacy Dyad." My dissertation was funded by National Association of Wholesalers (NAW) through the Distribution Education Research Foundation (DERF).

I am a tenured Professor in the Department of Pharmaceutical and Healthcare Marketing where I have taught since 1998. From 2003 to 2010, I was the chair of the department. I created the curriculum in the undergraduate and graduate programs as well.

I teach undergraduate courses for the undergraduate pharmaceutical and healthcare marketing program. I have taught courses in smart healthcare consumer, channels (supply chain management), pricing, marketing research and strategy (capstone) courses. On a regular basis, I take students to visit manufacturing, packaging, wholesaling and pharmacy facilities to see their operations as an experiential learning experience. I have been trained at Harvard in the case method I use in my teaching. I also teach Healthcare Marketing as a Visiting Professor on behalf of Wharton Business School in their global programs.

I have published articles in peer-reviewed journals, including the Journal of International Marketing, Journal of Operations Management, Journal of Business Venturing, Journal of Pharmaceutical Marketing and Management, International Journal of Pharmaceutical and Healthcare Marketing, Journal of Medical Marketing, Journal of Commercial Biotechnology, Journal of Research in Pharmaceutical Economics, International Journal of Healthcare Management, Information & Management. My curriculum vitae contains all my publications.

I have also presented papers in many conferences, including *American Marketing Association, Academy of Management, Informs, Decision Sciences, Pharmaceutical Management Science Association, Academy of Marketing Science, Public Policy and Marketing* and received several best paper awards.

My co-author Dr. William Doucette and I conducted a research study titled "Drug Wholesalers and Customers: Attitudes and Expectations of Current and Future Service Integration," funded by NWDA Healthcare Foundation. The research study was based on 40 interviews with leading chain drugs stores, independent pharmacies, group-purchasing organizations (GPOs) and integrated health systems (IHSs) in which the participants shared their expectations of the wholesalers. The 100-page report also showed that the customers wanted further integration with drug wholesalers in order to reduce distribution and administrative costs, allowing them to focus on patient care.

Some other notable work includes serving as an external reader for a dissertation in marketing at Columbia University. I have been quoted in Financial Times, Bloomberg, Boston Globe, and Pharmaceutical Executive publications among others. I am the recipient of the Extraordinary Achievement in Research award and the Extraordinary Achievement in teaching award at Saint Joseph's University. I am a member of Rho Chi (the honor society for pharmacy) and Beta Gamma Sigma (the honor society for business). I have also served as a consultant to several major pharmaceutical and healthcare firms conducting regular strategy planning sessions for senior executives among other work. From 2011 - 2012, I worked within Pfizer as part of the global commercial team and launched an adult indication of a vaccine worldwide. I also serve on the advisory board of the Downingtown STEM Academy, Downingtown PA.

III. Methodology

My analysis in this case is based on my education, training, industry experience, consulting, research, and publications. In my teaching, I use the case method and also employ theoretical frameworks from marketing, economics, organizational behavior, and psychology. This mix of theory and real-world examples has been effective for both my teaching and research work.

IV. Compensation

I am being compensated at $325 per hour for my time in this case.

V. Opinions

My opinions are based on my background, training, education, experience, and my review of the professional literature, among other things. All of my opinions are made to a reasonable degree of professional certainty.

Opinion 1: Marketing in the Pharmaceutical Industry Operates in a Highly Regulated Environment. Unlike other industries, marketing in the pharmaceutical industry is highly regulated with guidelines and regulations among other controls. Marketing, by definition, enables manufacturers to create acceptable products or services, meet customer needs, create awareness of the product or service *via* promotion, provide access to the products *via* distribution by supplying the product right time and place, and capture the value created by the product or service by appropriately pricing the product. Marketing, thus, is the process of creating value to the customers through exchange and capture the value created in the form of sales or revenue.

Opinion 2: Physician, Pharmacists, PBMs and Payers Determine Product Access to Patients. Unlike other industries, the physicians, pharmacists, PBMs and payers are the gatekeepers who control access to the prescription products for patients. Physicians are the learned intermediary whose expertise is in diagnosing the illness of the patient, determining the appropriateness of a prescription product, and having the legal authority to write the prescription for the product. The payer (insurer) agrees to cover or pay for the product, and the pharmacists have the legal authority to dispense the medications to the patients. Pharmacy Benefit Management (PBMs) are organizations that primarily administer outpatient drug benefits for payers. By managing the formularies of drugs, PBMs facilitate or restrict access to prescription medications. Thus, demand for the prescription product is driven by these four stakeholders.

Opinion 3: **Wholesalers Provide Logistical Support Creating Efficiency and Coordination in the Supply Chain Operating at a Razor Thin Margin**. In the pharmaceutical supply chain, wholesalers are middlemen who are primarily involved in the distribution of the products from the manufacturers to the several customers downstream, including retail pharmacies, mail order pharmacies, chain warehouses, hospitals, HMOs, and clinics. Manufactures also can directly distribute the products to the above-mentioned customers bypassing the wholesalers. Wholesalers through coordination create significant efficiency in the complex supply chain. Wholesaling in the healthcare industry is hypercompetitive and, as an indicator for their competition and efficiency, their average gross margins from 2007 to 2018 was 2.75% and their average net profit was 0.64% much less than any other member in the pharmaceutical supply chain.

Opinion 4: Wholesalers and Pharmacies are a Different Class of Trade. Wholesalers are a different class of trade compared to pharmacies. Unlike pharmacies, wholesalers do not interface or interact with the patient, are not involved in clinical decision consultation or discussion with the physicians, nor do they have the legal authority to dispense drugs to patients directly. Pharmacies, on the other hand, interface with patients, are involved in the clinical decision consultation with the physician, and have the legal authority to dispense the drug to the patients. From the trade classification standpoint, wholesalers do not have control over the number of prescriptions generated nor the product chosen to be dispensed to the patients in a market place.

Opinion 5: Coordination between Manufacturers, Wholesalers and Pharmacies Enhances Efficiency and Responsiveness of the Supply Chain. Coordination is necessary to deliver lifesaving high quality pharmaceuticals to the patients at the time the patient needs them. This is critical in a complex distribution process with varied customers, such as independent pharmacies, chain pharmacies, chain warehouses, mail order pharmacies, hospitals, clinics, HMOs and Nursing homes. Communication in the supply chain is imperative to coordinate business-related activities such as new product launches, managing chargeback payments, regulatory compliance, product security, product recall, process productivity, costs and risk in the supply chain.

Opinion 6: **Wholesalers' Role in Trade Promotions is Simply to Act as a Conduit for Manufacturer Information**. Like many other industries in a competitive market, product manufacturers in healthcare do trade promotions creating access for their products to the wholesalers and providers (pharmacies). Trade promotion is not unique to opioids, and, in fact, is more common for most branded pharmaceuticals and items in the front end of the pharmacy, such as OTC products. While wholesalers charge service fees to execute the trade promotion for the manufacturers and to communicate and educate the pharmacists about their products, they do not alter or modify the manufacturer's marketing material. The product and the label information is owned by the manufacturer and this is evident in many of the contractual "statement of work" documents reviewed. The wholesalers primarily manage the logistics of providing information to the pharmacies about the manufacturer's product. This information typically centers around the product's price, availability and quality to enable pharmacies to make better procurement decisions. With respect to demand creation for opioids, the wholesaler has the least power since the physicians, PBMs, payers and pharmacists control the prescribing, reimbursement, and dispensing of opioids. Thereafter, the provider makes the ultimate decision to buy or not. Notably, trade promotions in general are not very effective expect during new product launch.

VI. Basis and Reasons for Opinions

A. The Societal Benefit of Marketing

American Marketing Association (AMA) defines marketing as "the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large."[1] Marketing facilitates developing an acceptable product that: (1) satisfies an unmet need; (2) creates awareness of the product by communicating the value of the product to the stakeholders (such as physicians, patient and payers) *via* promotion; (3) makes the product accessible by executing a distribution strategy – also called place; and (4) offers the product to the customers, capturing the value created by using appropriate pricing strategy. *See* Table 1 below. High-performance marketing organizations can create the ability to leverage customer insights, demonstrate superior cross-functional collaboration, and achieve strategic focus.[2]

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[1] *Definitions of Marketing*, American Marketing Association, https://www.ama.org/the-definition-of-marketing/ (Last visited April 12, 2019).

[2] Moorman, C., Day, G.S., *Organizing for Marketing Excellence* (2016), 80 J. Mark, 6-35.

Table 1: 4 Ps, As, and Objectives Of Marketing

4 Ps	4 As	Objectives
Product	Acceptability	Address Unmet Needs
Promotion	Awareness	Communication Of Value
Place	Accessibility	Creating Access By Delivery
Price	Affordability	Value To Payers

Peter Drucker, a former Harvard Professor, states that "business has only two basic functions: marketing and innovation." Studies have shown that marketing creates economic efficiency by creating awareness about possible solutions to a problem, enhancing competition, creating economic efficiency, and demonstrating the positive predictive influence of marketing system on societal well-being and increase quality of life.[3] These findings are consistent with the many arguments made by marketing scholars about the positive contribution of marketing to society.[4]

Unlike consumer package goods and other products marketed in United States, pharmaceutical product marketing environment is highly regulated. In the section below, I will illustrate the extent of regulation overall of the industry and specifically marketing in in the industry.

B. Pharmaceutical Marketing in a Regulated Environment

1. Stringent Pharmaceutical Approval Process

Pharmaceutical companies bring to market products that benefits society and affect virtually every facet of the healthcare system. Pharmaceutical companies are involved in a high-stakes business to develop innovative products for which the failure rate is high and the reward of success is great. In pharmaceutical development, many promising leads prove disappointing, often after millions, if not billions, of dollars are invested in them. A recent study has shown that the probability of success for approval of drugs in phase I, phase II and phase III clinical trials are 9.6%, 31%, and 58%, respectively.[5] Another study has estimated the overall probability of success from phase 1 to approval is 6.2% across all disease states.[6]

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3 Sirgy, J. M., Yu, G.B., Lee, D., Huang, Wei S., *Does Marketing Activity Contribute to a Society's Well Being?* The Role of Economic Efficiency (2012), 107 J. Bus. Ethics, 91-102.

4 Kolyter, P., Jaturipitak, S., *The Marketing of Nations: A Strategic Approach to Building National Wealth.* New York, Free Press, 1998.

5 *Clinical Development Success Rate 2006-2015*, Biotechnology Industry Organization (2006), 7.

6 Wong, C.H., Siah, K.W., *Estimation of Clinical Trails Success Rates and Related Parameters*, 20 Biostatistics (2019), 273-286.

As part of the development process, pharmaceutical companies have to obtain product approval from the Food and Drug Administration (FDA). During this process, the clinical trials data collected by a company is submitted to a review committee at the FDA. The review committee, comprised of experts in a particular disease state and the approval process, conducts rigorous evaluation and votes to either recommend or not recommend the drug for approval to the FDA. The FDA would then decide either to approve or not approve the drug based the value perceived by the FDA, including opioids. As such, the FDA influences what types of pain medication are available within the supply chain. If approved, the product would obtain the label that has the claim or indication that the pharmaceutical company is allowed to communicate to the physicians, payers and patients.

A prescription drug product label (also known as a professional label, package insert, direction circular, or package circular) is a compilation of information about a product written by the manufacturer and approved by FDA. Labeling is based on the agency's thorough analysis of the new drug application (NDA) or biological license application. The labeling, or prescribing information, is thus subject to FDA regulations and is a requirement for all approved drug and biological drug products. A label contains information necessary for safe and effective use of the product and is written primarily for the healthcare practitioner. Products that have potential side effects would receive a "Blackbox" warning and might be required to conduct Risk Evaluation and Mitigation Strategies (REMS).

Importantly, manufacturers obtain approval from the FDA for these inserts and labeling and wholesalers have no control over that process. Further, the approved label can only be modified by the manufacturer based on further studies or data that justifies a change. The manufacture should go through the FDA for the label change. Notably, the product has to go through rigorous evaluation on manufacturing process and quality and obtain the approval for manufacturing to assure quality and safety for patients.

2. Regulations Enhance Generic Competition

Pharmaceutical companies receive 20 years of patent protection for the product innovation. After the FDA approval process, the effective product patent would be about 8-10 years during which the company would have to recoup the investment. Upon patent expiry, generic companies can enter the market to compete with the branded drug. Until 1984, generic companies had to conduct clinical trials to launch their generic versions of the drug. In 1984, the Generic Price Competition and Patent Restoration Act was passed that stipulated that generic companies only have to prove bioequivalence and do not have to conduct the complete clinical trials. The change in regulation led to more generic entries, which reduced the cost of the drug in the market.[7]

3. Pharmaceutical Promotion Regulation

[7] Jambulingam, T., Kreling, D. H., *Relationship Between the Number of Firms and Generic Price Competition*, 63 J. Pharmaeconomics, (1995) 39-60; U.S. Food & Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations,* https://www.accessdata.fda.gov/Scripts/cder/ob/search_product.cfm (Last Visited April 10, 2019).

The FDA strictly regulates pharmaceutical promotion under the Food, Drug, and Cosmetic Act of 1938. Until 1967, pharmaceutical companies were only able to share information about the products to physicians (no information was shared with patients). With the growing trend of consumerism,[8] Congress felt the need to provide more drug information to the consumers. Thus, in 1967, Congress enacted the Fair Packaging and Labeling Act that required manufacturers to provide drug information to consumers, and, in 1970, the FDA required manufacturers to provide information related to benefits and risks to consumers in the form of patient product inserts. This was the beginning of direct to consumer advertising.

Importantly, the FDA did not provide any guidelines regarding how manufacturers should promote to the general public till the 1980s. Until the early 1990s, only a few manufacturers tried direct to consumer advertising not really knowing how to communicate the product information to patients. In 1993, FDA started regulating the Direct to Consumer (DTC) advertising by requiring the manufacturers to include all side effects and contraindications in DTC advertising and requesting that manufacturers voluntarily submit marketing materials for review of all fair balance requirements. With lack of clear guidelines, manufacturers faced many challenges regarding how to effectively communicate the value of the product within the undefined parameters of the law.

In 1997, the first draft guidance on DTC was provided by the FDA and in 1999 the final guidance was published based on the input from different stakeholders. FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) was monitoring the advertising and promotions of the pharmaceutical products.[9]

In 2011, DDMAC changed its name to the Office of Prescription Drug Promotion (OPDP). The mission of OPDP, as stated in their website as "to protect the public health" by ensuring that prescription drug information is truthful, balanced, and accurately communicated.[10] This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.[11] OPDP, from time to time, provided guidelines to the industry on how the drug information should be shared and communicated to healthcare practitioners and patients.[12]

OPDP, formerly DDMAC, has several mechanisms to enforce compliance, such as issuing untitled letter or warning letters for promotions that do not comply with fair balance requirements

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[8] Donohue, J., *A History of Drug Advertising: The Evolving Roles of Consumerism and Consumer Protection*, 84 Milbank Q (2006), 659-699.

[9] Mogull, Scott, A., *Chronology of Direct to Consumer Advertising Regulation in the United States*, AMWA Journal, 23 (3) (2008), 106-109.

[10] U.S. Food & Drug Administration, *Office of Prescription Drug Promotion (OPDP) Research*, About FDA, https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm, (Last Visited April 11, 2019).

[11] *See id.*

[12] U.S. Food & Drug Administration, *Advertising*, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm, (Last Visited April 11, 2019).

or claims made in advertising that are not substantiated (such as efficacy, effectiveness, risk, quality of life, safety, tolerability). Untitled letters are issued when the violation is not significant enough to meet the threshold of regulatory significance. On the other hand, warning letters request a correction of the violation. Unlike a warning letter, an untitled letter does not include a statement that warns the individual or firm that failure to promptly correct the violation may result in enforcement action. To avoid untitled or warning letters, manufacturers typically voluntarily submit the promotional materials to the OPDP for review before they promote their products.

While manufacturers regularly submit the promotional material to OPDP, the FDA typically does not provide feedback in a timely fashion. In fact, FDA guidelines state there is no legal obligation to warn about violations before taking enforcement action. This puts the pharmaceutical companies in a bind. Unlike consumer goods, pharmaceutical product development and regulatory approval would take 10-12 years, leaving only about 8-10 years to commercialize the product before the patent is expired. With no guidance provided by the FDA, pharmaceutical companies interpret the FDA guidelines to the best of their abilities and develop the communication plan for their products.

In 1998, the number of letters issued by OPDP (then DDMAC) was 158 (7 warning letters and 151 untitled letters), but in 2018 only 9 letters were issued by OPDP (2 warning letters and 9 untitled letter). This remarkable statistic shows that when the FDA provides clear guidelines, the industry follows the promotional policy. Then notion that pharmaceutical companies purposely violate the fair balance requirements and provide improper advertising material is preposterous and unfounded. Because pharmaceutical companies understand that loss of credibility, trust, and reputation among physicians, pharmacists, payers and patients would come with significant financial costs. In a study I conducted on the impact of warning letters on the stock performance of 14 pharmaceutical companies, I found the market value loss of about $8 billion when warning letters are issued.

a) Bad Ad Program

In May of 2010, FDA launched the Bad Ad outreach program with the goal of encouraging healthcare professionals (HCPs) to recognize and report suspected untruthful or misleading prescription drug promotions. OPDP focused its efforts on educating HCPs about what constitutes misleading prescription drug promotion — from both a legal and clinical perspective — and providing them an easy process for reporting suspected violations to the FDA. The program engaged the physicians, patients, and pharmaceutical companies to be engaged and report any misleading advertisement with the FDA.

b) Risk Evaluation and Mitigation Strategies (REMS)

In 2007, FDA was given new authority to ensure safety of the drugs to the patients by creating a REMS (Risk Evaluation and Mitigation Strategies) program designed to ensure the benefits of a given product outweigh its risks to patients. In 2012, the FDA worked with various entities to develop and implement a REMS program for the drug class titled “Opioid Analgesics REMS.” The goals of the REMS for opioids is stated in the FDA website as follows:

> The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and

> monitoring of patients with pain. The education provided through the REMS program is based on the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"). Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies which is intended to assist healthcare providers in reducing adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse. The REMS will accomplish this goal by:
>
> 1. Ensuring that training based on the FDA Blueprint is effective in educating prescribers and other healthcare providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.
>
> 2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics.[13]

Following the above quoted information, are the generic names of products that are affected by this mandated REMS program.[14] As part of the REMS program, manufacturers are required to communicate with the providers creating awareness, education, registration and extensive data collection as part of the REMS program.

4. The Office of Inspector General (OIG) Guidelines [15] & The Pharmaceutical Research and Manufacturers of America (PhRMA) Code

By the late 1990s, the cost of healthcare in the USA surpassed the one trillion-dollar mark – four times the cost in 1980. The OIG identified pharmaceuticals as the single largest source of cost increases in federal healthcare programs and the greatest threat to their solvency. By 2001, the pharmaceutical companies employed 87,000 pharmaceutical sales representatives in the USA (twice the number recorded in 1996) and their spending on promotion reached $19.1 billion (an increase of 73 percent since 1997).

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[13] U.S. Food & Drug Administration, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17 (Last Visited April 10, 2019).

[14] *See id*.; Opioid Analgesic Risk Evaluation and Mitigation Strategies (REMS), *Products Search*, (2019) https://opioidanalgesicrems.com/RpcUI/products.u.

[15] Office of Inspector General, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731-23743 (2003), https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

This increase in promotional spending combined with spiraling healthcare costs led to heightened scrutiny of pharmaceutical firms' marketing practices such as gift-giving, educational grants, product sampling, and physicians' inducements to "switch" prescribed drugs. These developments also led the OIG to undertake preventative measures and issue new guidance to the industry. On June 11, 2001, the OIG published a solicitation notice seeking information and recommendation to develop compliance program guidance for the pharmaceutical industry.[16] In response to the solicitation notice, the OIG received eight comments from various outside sources.[17]

On April 18, 2002, PhRMA (2002), the trade organization representing the pharmaceutical research manufacturers, issued its own code (the "PhRMA code") providing guidance (a preemptive move in the form of self-imposed regulation) to its members pertaining to their interactions with the physicians.[18] The PhRMA code had specific sections to address the concerns raised by the OIG in its "call for information" notice. They are listed below:

- General interaction. Interaction should focus on informing the healthcare professional about scientific and educational information and supporting scientific medical research and education to maximize patient benefits.

- Entertainment. Interaction should not include entertainment. Interaction should occur at a venue conducive to providing scientific or educational information. Specifically, this means no "dine and dash," no entertainment, and no recreational events (for example, sporting events or spa visits).

- Continuing education. Companies can provide support to the conference sponsor but should not fund individual participants. This means a company should not pay an individual's tuition, but could provide support to the event sponsor. That sponsor may in turn provide grants to individuals to participate, or to reduce the overall registration fees for all attendees.

- Consultants. Legitimate consulting or advisory arrangements are appropriate; but token consulting arrangements should not be used to justify payments to healthcare professionals. Characteristics of legitimate consulting arrangements include the retention of professionals based on their expertise, not as an award or inducement for prescribing, and retaining no more consultants than needed for the specific program.

- Educational and healthcare practice-related items. Educational and practice-related items may be provided to healthcare professionals, but should be for the healthcare benefit of patients and of less than substantial value ($100 dollars or less). Items for the personal benefit of the healthcare professional should not be

[16] *See id.*

[17] *See id.*

[18] PhRMA, *Code on Interactions with Healthcare Professionals*, (Feb. 2, 2017), https://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals.

> offered or distributed. In short, nothing should be offered or provided that would interfere with the independence of the healthcare professional's prescribing practices.[19]

On October 3, 2002, following the PhRMA code, the OIG published the draft version of the compliance program guidance in the Federal Register inviting responses from the stakeholders.[20] The draft provided a mechanism that addressed the public and private sectors' mutual goals of reducing fraud and abuse; enhancing healthcare provider operational functions; improving the quality of healthcare services; and reducing the cost of healthcare. The draft explicitly suggested to the pharmaceutical companies to voluntarily establish a comprehensive compliance programs within the companies, and that the companies should make a good faith effort to comply with applicable statutes and regulations as well as federal healthcare program requirements. The draft identified three specific areas of risk that the industry has to comply with. They were:

(1) assurance of integrity in reporting of pricing data used by state and federal governments to establish payment;

(2) kickbacks and other illegal remuneration by which pharmaceutical companies offer benefits to providers with the intent of generating business such as pay pharmacist, physicians or others to switch patients from a competitor drug to the company's product; and

(3) compliance with laws regulating drug samples and not to bill or sell free drug samples to federal healthcare programs by providers or companies[21].

In addition, the draft pointed out industry practices that had high potential for abuse and could potentially violate anti-kickback statue such as:

- entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations;
- sponsorship or other financing related to third-party educational conferences and meetings attended or taught by physicians or others in a position to generate or influence referrals;
    - scholarships and educational funds;
    - grants for research and education; and
    - gifts, gratuities, and other business curtsies[22].

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[19] *See id.*

[20] Office of Inspector General, *Draft OIG Compliance Program Guidelines for Pharmaceutical Manufacturers*, 67 Federal Register (2002), 62057-67.

[21] *See id.*

[22] *See id.*

The draft specifically noted that the PhRMA code as proposed by the industry would serve as the "minimum standard" of behavior and may not "necessarily protect a manufacturer from prosecution or liability for illegal conduct."

The OIG received 142 responses to the draft. There were 26 responses from medical associations and specialty societies, 14 from the pharmaceutical industry and the remaining 102 from consumers, HMOs, providers, pharmacy benefit managers (PBMs), and state health departments. In addition, the OIG met privately with representatives from medical organizations, the pharmaceutical industry and private healthcare plan and PBMs.[23] Some medical organizations such as American Medical Associations (AMAs) and Association of American Medical Colleges, protested the draft guidance suggesting that limitations to pharmaceutical company's funding might jeopardize educational activities of physicians and that their codes of ethics already specify that the educational activities be independent of commercial interests. In addition, the medical organizations requested the OIG to leave the oversight of the pharmaceutical industry-funded research grants and consulting arrangements up to the universities and medical centers arguing that their own review boards ensure that researchers do not receive improper inducements from the pharmaceutical companies[24].

Based on the input from all the constituencies, the OIG revised its guidance and published the final report in the Federal Register on May 5, 2003. The following seven elements were considered to be the "core" of an effective and successful corporate compliance program:

(1) Implementing written policies and procedures.

(2) Designating a compliance officer and compliance committee.

(3) Conducting effective training and education.

(4) Developing effective lines of communication.

(5) Conducting internal monitoring and auditing.

(6) Enforcing standards through well-publicized disciplinary guidelines.

(7) Responding promptly to detected problems and undertaking corrective action.

The objective of the guidelines was to influence the pharmaceutical companies to self-regulate their business practices thus reducing their ability to "influence" and/or "reward" physicians. The "guidance" by the OIG falls between a self-regulation by an industry and a regulation or an act passed by the government. Self-regulation is voluntary in nature, involves planning and public policy making that concern issues and activities not covered by public regulation. It does cover

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[23] Chimonas, S., Rothman, D.J., *New Federal Guidelines For Physician-Pharmaceutical Industry Relations: The Politics Of Policy Formation* (2005), 24 Health Affairs, 949-60.

[24] Office of Inspector General, *Draft OIG Compliance Program Guidelines for Pharmaceutical Manufacturers*, 67 Federal Register (2002), 62057-67.

behavior that is discretionary.[25] Self-regulation exists when a firm, an industry (or profession) establishes its own standards of behavior:

- where no such statutory or regulatory requirements exists; or
- when such standards assist in complying with or exceeding statutory or regulatory requirements.[26]

Generally, when self-regulation is contemplated, participants in the conversation are referring to a code of conduct or ethics laid out in a document that clarifies what behavior standards are sanctioned.[27] Garvin recommends that the greatest potential for self-regulation lies in mixed systems, combining industry association rule making with federal oversight. Gupta and Lad concur, arguing that some form of government guidance oversight and threat of direct regulation often coexists along with industry's self-regulation.[28] Thus, the OIG guidance provided a regulatory framework for the industry.

5. Sunshine Act

Beginning August 1, 2013, the Physician Payments Sunshine Act (the "Sunshine Act"), which is part of the Affordable Care Act, requires manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal healthcare programs to track and then report certain payments and items of value given to U.S. physicians and U.S. teaching hospitals (defined as "Covered Recipients"). The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services (CMS) by the 90th day of each subsequent year[29]. On June 30th of each year, CMS posts the reported payments and other transfers of value on its public website.[30]

6. Prescription Drug Marketing Act

The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law on April 22, 1988. The PDMA was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, sub potent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard,

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[25] Wotruba, T.A., *Industry Self-Regulation: A Review And Extension To A Global Setting*, 16 J. Pub. Pol'y & Mark. (1997), 38-54.

[26] Hemphhill, David F., *Self- Regulating Industry behavior: Antitrust Limitations and Trade Association Code of Conduct*, 11 J. Bus. Eth. (1992), 11.

[27] Gupta, Anil K., Lad, Lawrence J., *Industry Self-Regulation: An Economic, Organizational, and Political Analysis*, 8 Academy of Management Review (1983).

[28] Garvin, D.A., *Can Industry Self-Regulation Work?,* 25 Cali. Management Rev. (1983), 37-52.

[29] Department of Health and Human Services, Medicare, Medicaid, Children's Health Insurance Programs; *Transparency Reports and Reporting of Physician Ownership or Investment Interests*, 76 Federal Registrar, 78742-78773 (2011).

[30] Richardson, Elizabeth, *The Physician Payments Sunshine Act*, Health Affairs (Oct. 2 2014).

ineffective, or counterfeit drugs.[31] The act prohibits the diversion of prescription drugs or biological products to illegitimate commercial channels or supply chain. It also prohibits the sale of drug samples. The law provides that companies must obtain the signature of a physician for all drug samples. The law requires record-keeping and careful storage of samples.

7. Controlled Substance Act (CSA)[32]

The CSA shows how regulations and compliance impact managing the supply chain. It provides a framework for the federal government to regulate the lawful production, possession, and distribution of controlled substances. The CSA places various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. Further, the CSA requires persons who handle controlled substances or listed chemicals (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers) to register with the Drug Enforcement Administration (DEA) in the U.S. Department of Justice (DOJ), which administers and enforces the CSA. DEA sets the yearly limit or quota on volume of opioids that can be manufactured. The registrants have to report the sales of opioids to the DEA through the Automation of Reports and Consolidated Orders System (ARCOS) system. The system is not available to any of the registrants who report into the system. This data would have detailed data by registrant that can be helpful to track suspicious orders and limit excessive number of opioid prescriptions.

- Drug manufacturers that design, develop and promote the medication
- Healthcare providers who prescribe the medication
- Wholesalers who distribute the medication
- Pharmacists who dispense the medication
- Private and public health insurance groups that determine what they will pay for
- State medical and pharmacy boards that oversee the doctors and pharmacies in their jurisdiction

Universal access to the ARCOS data would make the system more transparent especially when, for example: a pharmacy is buying from multiple wholesalers or combining its purchases with direct purchasing, which no one wholesaler would be able to determine.

8. Drug Supply Chain Security Act 2013

In addition, in 2013, The Drug Supply Chain Security Act (DSCSA) was enacted requiring the pharmaceutical distribution for prescription drugs be traced throughout the supply chain. By 2023, drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily

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[31] U.S. Food & Drug Administration, *Prescription Drug Marketing Act of 1987*, (March 28, 2018) https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/prescriptiondrugmarketingactof1987/default.htm.

[32] United States Drug Enforcement Administration, *The Controlled Substances Act,* https://www.dea.gov/controlled-substances-act (Last Visited on April 12, 2019).

pharmacies) will have to work in cooperation with FDA to develop the new system. The new system will:

- Enable verification of the legitimacy of the drug product identifier down to the package level;
- Enhance detection and notification of illegitimate products in the drug supply chain; and
- Facilitate more efficient recalls of drug products.

By 2023, the supply chain should take steps to steps comply with the DSCSA requirements by achieving the following objectives:

- **Product identification**: Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing**: Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing**: Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

In summary, the pharmaceutical marketing environment, which includes product development, has various regulations for the different entities. The wholesaler, which is very involved in the distribution of the manufacturer's product (one of the 4 Ps of marketing) plays a very important role in the safe and secure distribution of the products. However, it plays an insignificant role in the area of product demand and no role at all in product development, packaging, or labeling. Importantly, without wholesalers the efficiency of the supply chain would suffer along with the fast and reliable way in which patients receive important and life-saving medication.

C. Physician, Pharmacist, Payers, and PBMs Determine Product Access to Patients

Pharmaceutical manufacturers invent and commercialize the products to meet patient needs. Pharmaceuticals are classified as Rx and non-Rx products. Rx pharmaceuticals can be branded and generic. All Rx products have approved label and the manufacturers use the label to promote their products to physicians, pharmacists, payers, and patients using varied promotional methods. Physician promotion might include sales representative calls, advertising in medical journals, meetings and events, samples, paid speaker programs, and digital and direct marketing.

1. Physician

Physicians are the gatekeepers with authority to prescribe the products. Physicians go through a rigorous educational training, obtain board certification, and are licensed by the state medical board to practice medicine. Physicians are considered experts in medical diagnosis and appropriate treatment of patients. A physician could be primary care physician, specialist, or dentist, who can prescribe products. In a study conducted in the U.S., physicians rated the importance of the resources for their practice. The ratings, in the order of importance, are medical books, medical journals, symposia/conferences, free samples, [33] other physicians, pharmaceutical industry representatives, medical guides, pharmaceutical brochures/ads, local dinner meeting, lunch with sales representatives and medical expos/trade conventions.[34] Another study looked at factors that physicians consider when prescribing. Those factors included, in order of importance: clinical knowledge & experience, patient's unique situation, peer-reviewed journals, clinical practice guidelines, colleagues and peers, patient's financial status, patient's coverage and formularies, information from pharmaceutical company reps, patient's personal opinions, prior authorization restrictions, and the amount of the co-pay and information from insurance companies and PBMs representatives.[35]

Dr. Matthew Perri illustrates the information-processing model that physicians use in prescribing a product on page 15 of his expert report.[36] The physician might obtain the stimuli (exposure) to the drug information from a pharmaceutical industry or non-pharmaceutical industry sources. Through the cognitive process of attention, comprehension, and acceptance, physicians retain the information in their memory. Based on the diagnosis of a patient condition, the physician would do an internal search, identify the treatment options based on what is retained in their memory, evaluate the options based on the benefits, risks, payer coverage, formulary status, affordability of the drug to the patient, etc., before they prescribe the drug to the patient. Physicians might also consider the treatment guidelines of their health system, professional associations' guidelines, and

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[33] Note: Scheduled products are not sampled.

[34] Spiller, L.D., Wymer Jr., W.W., *Physicians' Perceptions And Uses Of Commercial Drug Information Sources: An Examination Of Pharmaceutical Marketing To Physicians*, 19 Health Mark. Q., (2001) 91-106.

[35] PhRMA, *Pharmaceutical Marketing in Perspective, Its Value and Role as one of Many Factors Informing Prescribing*, http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_brochure_influences_on_prescribing_final.pdf.

[36] Expert Report of Dr. Matthew Perri III, p. 15 (Mar. 25, 2019).

patient input. For controlled substances, the prescriptions should include the DEA number to prescribe the product.

There are many factors that could lead a physician to prescribe opioids. First, the physician might have a genuine intent to help the patient with pain. Second, the physician might prescribe the product in the multiple of 30, one per day or for mail order prescription 90-day supply. Ronald Hirsch, M.D., in 2017, wrote an article titled "The Opioid Epidemic: It's Time to Place Blame Where it Belongs."[37] In his article, he states the reason for overprescribing of opioids by the physicians:

> In all fairness, I will start with physicians. We overprescribe opioids, just as we overprescribe antibiotics. But it is generally well meaning; we don't want our patients to experience pain. But then we prescribe 30 or 60 pills when 5 or 20 would have been adequate. We do that because we are used to prescribing in multiples of 30; 30 days for a month supply of a once a day medication, 90 days for a mail-order prescription. Prescribing 6 or 10 pills will undoubtedly result in a phone call from a pharmacist asking for a round number of pills, taking up time better spent entering meaningless information into our electronic health record systems. It is the leftover pills that sit forgotten in the medicine cabinet which often lead to trouble, stolen by a relative or visitor and abused.

Another quote from Dr. Hirsch about physicians who abuse the system:

> We were truly trying to help the patient. But there are also what are known as "pill mill" doctors who set up shop, accept cash as the only payment and are willing to prescribe to anyone for any ailment, real or feigned.[38]

It is important to note that when a patient gets the prescription, given the lack of coordinated monitoring system, the patient can fill the prescription in different pharmacies obtaining multiple prescriptions for different physicians. This is called polypharmacy.

There are treatment or professional guidelines that could have influenced a physician's prescribing behavior. To illustrate a few, first the American Pain Society in the mid-1990s ran a "pain as the 5th vital sign" campaign to highlight the importance of pain and the lack of regular assessment by physician during office visits or even in the hospital after surgery. In 2001, the Joint Commission rolled out its Pain Management Standards, which helped grow the idea of pain as a "fifth vital sign." It required healthcare providers to ask every patient about their pain, given the perception at the time was that pain was undertreated and that the patient have the right to manage their pain.

Following the Joint Commission initiative, CMS developed an innovative approach to deliver care by moving from volume-based care to value-based care model. As part of the value-based care approach, the healthcare facilities were assessed using a survey called "Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) on seven constructs. They are

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[37] Hirsch, Ronald, *The Opioid Epidemic: It's Time to Place Blame Where it Belongs*, 114 Missouri Medicine (2017), 82-83, 90.

[38] *See id.*

Mortality, Safety of Care, Readmissions, Patient Experience, Effectiveness of Care, and Timeliness of Care. Patient experience is measured on an eleven items scale and one of the items is "patient who reported that their pain was well controlled."[39] Using the HCAHPS survey results the hospitals and health systems were rated on a health STAR rating ranging from 1 to 5. The higher the rating the better the reimbursement from CMS. It is conceivable that this survey could have motivated to overprescribing of pain medications including opioids.

2. Pharmacist

Pharmacists, similar to physicians, are licensed to practice by the state pharmacy board and authorized to dispense medicines to patients. Pharmacists are responsible for supplying quality medicines to patients, ensuring that the supply of medicines is within the law, ensuring that the medicines prescribed to patients are suitable, and advising patients about medicines, including how to take them, what reactions may occur, and what questions patients have. Pharmacists also supervise the medicine supply chain, ensure pharmacy premises and systems are fit for purpose, advise other healthcare professionals about safe and effective medicine use and safe and secure supply of medicine, respond to patients' symptoms, advise on medicines for sale in pharmacies, provide services to patients, such as smoking cessation, blood pressure measurement and cholesterol management, and supervise the production and preparation of medicines and assessments of quality of medicines before they are supplied to patients from pharmaceutical manufacturers.

Licensed pharmacists practice primarily in community retail pharmacies and in hospitals. When a prescription is received either electronically from the physician office or *via* a paper prescription from the patient, the pharmacist has to check the authenticity of the prescription, check for all legal requirements, including the DEA number, before they decide to fill the prescription. Unless the prescription states that it has be dispensed as written (DAW) or the drug is only available as a brand, the pharmacist can substitute the drug with an alternative. For example, instead of a branded product the pharmacist can switch to a generic if available. Normally, the payers would provide an incentive for the pharmacist to make the switch when a low-cost alternative is available.

3. Payers

Payers pay for the prescriptions as part of the pharmacy benefit. Payers are classified into private third-party payers (TPP), such as Aetna, Cigna, Humana, CMS (for Medicare Patients), Medicaid, and Cash paying patients. CMS administers payments, but the third-party insurance companies manage the insurance.

For payers, cost is the number one factor for coverage and reimbursement. Payers use formularies to manage products. Generics are covered in tier 1, preferred brand in tier 2, and non-preferred brands are in tiers 3 to 5. The higher the tier the higher the copay or coinsurance for the patient. In general, the generic opioid would be in tier 1, low copay for the patient and the brands would

[39] Centers for Medicare & Medicaid Services, CMS.gov, *Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS): Patients' Perspectives of Care Survey* (Dec. 21, 2017) https://www.cms.gov/Medicare/Quality-Initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalhcahps.html.

be in tiers 2 to 5. For example, Fentanyl transdermal patch or oxycodone (generic Oxycontin) would be in tier 1 and Oxycontin would be in tier 2 as preferred brand. Payers reimburse generics based on average price (maximum allowable cost) of generics in the market. As more generics enter the market, the competition intensifies and the cost of the medication drops leading to cheaper prices and greater access to products.

4. Pharmacy Benefit Management Companies (PBMs)

PBMs, such as Express Scripts, administer and manage the pharmacy benefit plan of the payers. PBMs process pharmacy claims for the pharmacies. When a physician generates a prescription, the pharmacist fills the prescription. The pharmacist would collect the copay from the patient and then submit the claim (the remaining cost of the drug along with a service fee for the pharmacist) to the PBM. The PBM then processes the claim, checks if the claim is submitted as per the contract with the payer, and then makes the payment to the pharmacy. The PBM then goes back to the payer and collects the cost of the claim to the PBM along with a service fee for processing the claim to the payer.

PBMs help the payers to make decisions on formularies and other cost control mechanisms for pharmaceuticals. Large PBMs like Express Scripts manage many different plans for different payers. In addition, PBMs engage in contractual relationships with the manufacturers on market share programs and obtain rebates from the manufacturer. The PBMs in turn will share the rebates with the payers. PBMs can also control what drug is being used. This primarily applies to branded pharmaceuticals. Thus, the PBMs have influence on what branded drug is filled by the pharmacy.

In summary, the physicians (by prescribing appropriately), pharmacists (by dispensing appropriately), payers (by reimbursing and/or limiting access appropriately), and PBMs (by participating in market share programs yet saving cost for the payers) all contribute to access to drugs in general, including opioids.

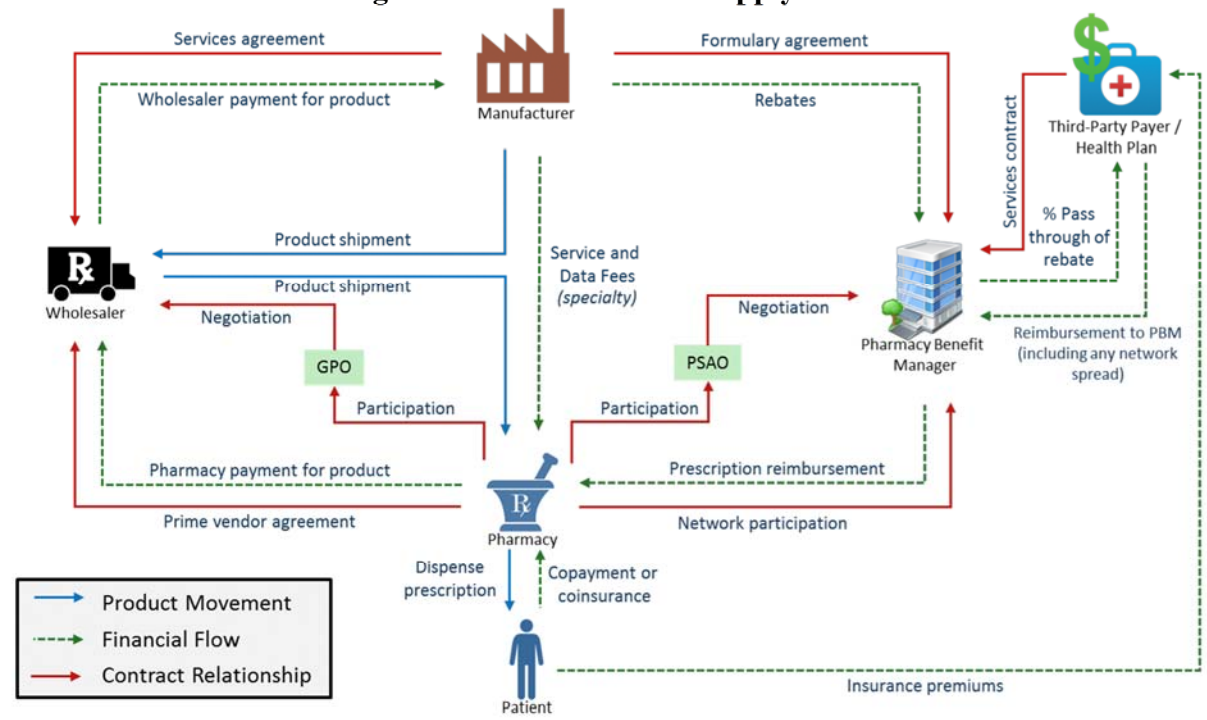
D. The Pharmaceutical Supply Chain and the Role of the Wholesaler[40]

The pharmaceutical supply chain is a complex, yet striving to be a coordinated system, that creates efficiency and responsiveness by delivering the right product, in the right quantity and condition, at the right time and place, for the right price and to the right customer.

Figure 1 (below) illustrates this architecture of the pharmaceutical supply chain. Pharmaceutical manufacturers supply majority of the products through the wholesalers to the pharmacies and other customers. Manufacturers have a distribution service agreement to supply products to the wholesalers. The manufacturer ships the physical product to the wholesaler who in term supply the product to the pharmacies and other customers (not to patients).

[40] Fein, Adam J., *The 2017-18 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Drug Channels Institute (2018).

Figure 1: Pharmaceutical Supply Chain

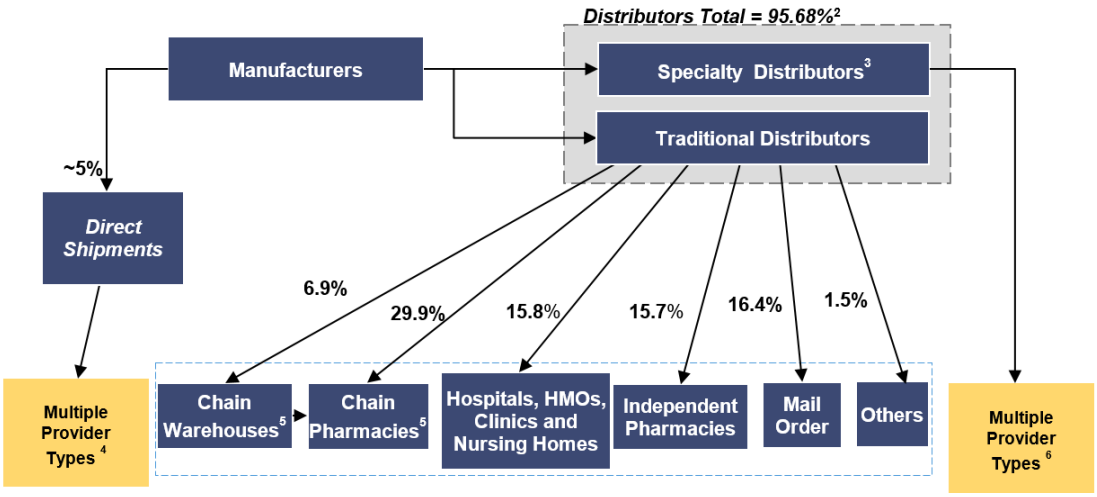


GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization
Source. Drug Channels Institute research. Chart illustrates flows for Patient-Administered, Outpatient Drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of product movement, financial flow, or contractual relationship in the marketplace.

Figure 2 (below) illustrates the proportion of the downstream supply of the products distributed by the wholesaler to different customers, such as independent pharmacies, chain pharmacies, chain warehouses, hospitals, HMOs, clinics, nursing homes, and mail order pharmacies. About 95% of the drugs pass through the wholesalers and the rest (5%) is directly shipped by the manufacturer to pharmacies and other outlets.[41] The pharmacy dispenses the prescription to the patient upon receiving the prescription from the physician. The pharmacy collects the copay from the patient and submits a claim to the PBM or directly to a payer for reimbursement. PBMs process the claim and make the payment to the pharmacy. The PBM will them collect the reimbursed amount along with a service fee from the payer.

[41] The independent pharmacy segment can join the prime vendor contract with the wholesaler and, as per contract, they typically agree to purchase majority of the products from that wholesaler in-turn for a fee the wholesaler provides varies services to the pharmacies. I will discuss those services later in my report.

Figure 2: The Flow of the Products in the Pharmaceutical Supply Chain[42].



1) Total value of goods flowing through the supply chain as per IQVIA. Percentages represent contribution by channel towards the total flow of $450BN.
2) Total value of goods flowing through traditional distributors, 2017-2018 HDA Research Foundation Factbook (Tables 2, 3) — excludes all non-prescription products, and sales to other distributors.
3) Specialty distributors defined as per the Specialty Pharmaceuticals: Facts, Figures and trends published by the HDA Research Foundation December 2017.
4) Manufacturers ship directly to Multiple provider types, including those served primarily by pharmaceutical distributors.
5) Chain pharmacies include national and regional drug store chains, mass merchandisers and food stores. Chain warehouses represent centralized warehouses for chain pharmacies.
6) Specialty distributors provide services to many provider types, including physicians' offices and clinics, home care providers, hospital pharmacies and specialty pharmacies.'

Given the working relationship of the PBMs with the pharmacies, the payers (on a yearly basis) depute the PBMs to create a network of pharmacies for their members to have access to pharmacy services. PBMs process millions of claims and have access to tremendous amount of utilization data that they use to create formularies for the payers. The payers have a service contract with the PBMs, and the payers pay a service fee based on value of processed claims and other services provided to the payers. Since the PBMs have influence over the creation of the formularies, the manufacturers working with the PBMs develop agreement to preferentially place their products on the formulary. Based on the performance of the drug, the manufacturer would provide rebates to the PBMs. The PBM in term share the rebate with the payers. This clearly shows that the physicians, pharmacist, payers and PBMs have impact on the demand of a product use.

In an earlier section, I discussed the regulations that affect the supply chain. In this environment, high levels of coordination are necessary to make the system safe and secure and protect the patients. Since wholesalers supply more than 95% of the products they have to coordinate with the manufacturer and pharmacies to comply all the regulations both federal and states regulations. In

[42] HDA Research Foundation, *The Facts, Figures and Trends in Healthcare (2017-2018),* 88 HDA Factbook (2017), 2.

a recent study I conducted with the pharmaceutical supply chain executives on the top 10 issues in the pharmaceutical supply chain, channel coordination is one of the top 10 issues in the industry.[43] Channel coordination is of paramount importance since it is imperative that the industry avoid product shortages, manage regulatory compliance, and manage risk in the system. To achieve these outcomes process integration is necessary to coordinate the distribution system.

Wholesalers add significant value in the supply chain by performing the following functions in an effort to preserve and maintain the systems integrity and avoid the issues noted above. Specifically, wholesalers:

- Aggregate demand across many small buyers: For instance, if a pharmaceutical manufacturer had to distribute products to 60,000 pharmacies individually, it would lead to 60,000 transactions. But, by introducing a wholesaler, the logistics experts in the supply chain, the manufacturer's transaction will drop to one because the wholesaler supplies to the 60,000 pharmacies downstream. This saves costs for the manufacturer because the wholesaler aggregates demand across all the pharmacies for the manufacturer.

- Allow manufacturers to produce steady quantity of product: The wholesaler can share the product demand data that the manufacturer can use to forecast, plan, and produce a steady quantity of drugs avoiding shortages and preventing excessive inventory build-up.

- Resolve discrepancy between the manufacturer and the pharmacy: A pharmaceutical manufacturer can only produce limited number of drugs (based on patent rights). On the other hand, a pharmacy might need multiple medications for patients with varied health conditions. These medications may be from different companies and one manufacturer cannot meet those needs. In addition, it is efficient for a manufacturer to supply in bulk with monthly deliveries, but the pharmacy needs small quantities of varied drugs preferably delivered once or twice a day. This creates a discrepancy in the supply that the wholesaler resolves by meeting the pharmacy's wants (desire small quantities of many different products) and manufacturer needs (produce large quantities of a few products). Thus, the wholesaler creates efficiency in the supply chain.

- Simplify the supply process through automated means: The wholesaler has an established distribution agreement with manufacturers and pharmacies and, in order to simplify the supply process, automates ordering process, inventory management process, payment process, billing process, and recall process, among other processes, to improve efficiency in the supply chain.

[43] The rest of the factors include shortage avoidance, sales and operations planning, inventory management, IT systems integration, regulatory compliance, risk management, strategy development, temperature control, and demand forecasting.

- Simplify credit issues for manufacturer in dealing with small pharmacies: The wholesaler will assume the risk of small pharmacy's risk with business challenges in including financial challenges and provide the credit record required to buy a manufacturer's products.

- Allow manufacturers to ship products in large batches by "breaking lots": The wholesaler, using its repackaging license, can break down large pallet size lots into small batches that it can ship to meet the demands of the pharmacies.

- Create a network of regional distribution centers to service the local customers: The wholesaler creates a network of distribution centers, where each one will serve all the pharmacy customers within a radius. This enables the wholesaler to receive the order late in evening from a pharmacy, pick, pack and ship to the pharmacy by 6 a.m. the next morning.

- Protect the quality and integrity of the product though proper storage and handling: The wholesaler is a registered, licensed facility, with state of the art security systems to prevent counterfeits, to manage control substances, have secure storage capability, handle with utmost care, manage shortages and deliver products safely.[44]

1. Manufacturer and Wholesaler Relationship

The objective of the partnership between manufacturers and wholesalers is to accomplish the following goals: (1) protect the product supply chain from grey market agents and counterfeits, (2) ensure product integrity, and (3) be a trusted distributor of the products.

Wholesalers provide specific services to the manufacturers to achieve those objectives, including:

- Business continuity risk management;
- Charge back administration;
- Customer access and knowledge;
- Data services: basic e.g. sales, inventory, returns;
- Data services: enhanced e.g. clinical performance;
- Disaster preparedness;
- Support compliance with federal and state regulations;
- Inventory management;
- New product launch support (product availability);
- Order management and fulfillment;
- Ownership of credit risk (receivables);
- Packaging and re-packaging services;
- Product compliance support services;
- Promotional material distribution;
- Provide 3rd party support services (contract review, reimbursement support);

[44] Burns, Lawton R., *The Healthcare Value Chain: Producers, Purchasers and Providers*, (Jossey-Bass 2002).

- REMS support;
- Reverse logistics / returns;
- Recalls;
- Security;
- Special handling services;
- Suspicious order monitoring; and
- Web based portal services.[45]

Reasons to work together with manufacturer: There are several reasons why manufacturers and wholesalers have to work collaboratively and coordinate the supply chain. First, it the manufactures' product that goes through the supply chain and product quality, integrity and safety have to be protected. Second, regulatory requirements due to the DSCSA, CSA, the Pharmaceutical Marketing Act, and the State Boards of Pharmacy rules, necessitate coordination between the parties to maintain regulatory compliance. For example, DSCSA requires an integrated technology to track every drug in its primary packaging all along the supply chain. This requires manufacturers, working with wholesalers and pharmacies to implement the Act. Third, products like opioids have class level REMS and wholesalers have a role in coordinating those programs for patient safety. Fourth, product recalls, disaster preparedness and planning for business continuity risk require coordination. Fifth, the manufacturer has to manage the chargeback process.[46] Finally, when a new product is launched the product has to be distributed to the pharmacies for product access before the prescription is written by the physician.

Thus, manufacturers must work with wholesalers to distribute products to pharmacies to comply with the law and the basic business arrangements between the parties. This is not specific to a product category, even though some additional requirements, per the CSA, must be followed with regard to some drugs.

The wholesalers also sometimes participate in the distribution of the manufacturers' promotional material. This is called trade promotion. As explained above, the wholesaler cannot and does not alter or modify the manufacturer's marketing material. The trade promotion targets the pharmacies, not the end consumer or patients. Trade promotion is not unique to opioids as it is applied to all types of products. Further, research conducted by Nielsen shows that trade

[45] HDA Research Foundation, *Understanding Pharmaceutical Distribution* (2017), https://www.hda.org/resources.

[46] A chargeback occurs when a manufacturer sells a product to the wholesaler at a contracted price. But the manufacturer negotiated another contract price with the chain pharmacy. The wholesaler has to supply the product as per the contract price between the pharmacy and the manufacturer, but if that price is less than what the wholesaler paid to obtain the product, the wholesaler will lose money. So, the wholesaler, after supplying the product to the pharmacy, will collect the difference in price from the manufacturer. This is a complex process to track all the price differences across all the products by manufacture to get the money form the manufacturer requiring complex negotiations. Manufacturers typically create the chargeback process, which is an expensive and arduous process of keeping track of all the contracts to recoup the cost by the wholesalers. It can become contentious between the manufactures and the wholesalers when they have to negotiate payments.

promotions in general are not very effective.[47] Importantly, the provider makes the ultimate decision to buy the product or not.

2. Pharmacy and Wholesaler Relationship

Wholesalers provide specific services to the pharmacy customers, including:

- Adherence/compliance programs and tracking;
- Business continuity risk management;
- Centralized information and improved communication flow;
- Charge back administration;
- Disaster preparedness;
- Support compliance with federal and state regulations;
- Financial management / access to credit;
- Inventory management;
- Order management and fulfillment;
- Payer economic modeling and negotiation support;
- Pharmacy management systems and services;
- Planogramming services;
- Product compliance support services;
- REMS support;
- Rack-Jobbing (in-store replenishment);
- Reconciliation services;
- Reverse logistics / returns;
- Recalls;
- Security; and
- Special handling services.

In addition, with respect to control substances, wholesalers:

- Review pharmacy licenses, registration and other information prior to providing prescription drug products; and
- Prior to shipping certain control substances (e.g. opioids), may conduct further review, including:
  - Visit the pharmacy location;
  - Examine historical dispensing data from the pharmacy;
  - Evaluate pharmacy expected order quantities for control substances; and
  - Monitor pharmacy orders on an ongoing basis.

Reasons to work with the pharmacy: As an initial matter, close working relationships with pharmacies enable wholesalers to balance their relationship with the manufacturer.[48] Specifically,

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[47] The Nielsen Company, LLC, *Trade Promotion Doesn't Have To Be A Guessing Game*, http://viz.nielsen.com/tradepromotionperformance/ (Last Visited April 8, 2019).

[48] Jambulingam, T., Kathuria, R., J.R., Nevin, *How Fairness Garners Loyalty in the Supply Chain: Role of Trust in the Wholesaler Pharmacy Relationship*, 3 Int'L J. of Pharm & Healthcare Mark. (2009), 305-322; Doucette, W.

the wholesaler's relationship with the pharmacy prevents the manufacturer from bypassing (disintermediation) the wholesaler and going directly to the pharmacy.

This actually indicates the lack of power the wholesaler has in the supply chain. Essentially, the wholesaler focuses on (1) developing close relationships with independent pharmacies, (2) offering chain pharmacies to outsource the warehousing function to the wholesaler, and (3) diversifying the customer base by supplying to other customers like PBMs for the mail order business, Group Purchasing Organizations (GPOs), specialty pharmacies, hospitals, and clinics.

AmerisourceBergen's Good Neighborhood Pharmacy (GNP) is a prime vendor program offered as a service to independent pharmacies. Independent pharmacies do not have the business acumen to run an effective store and many of them go out of business due to lack of business skills. Wholesalers, through programs like GNP, provide the business skills that enable the pharmacy to manage their inventory, cash flow, front-end merchandise, and generic source program, among other things—to effectively run the pharmacy. As part of the GNP program, a pharmacy would use AmerisourceBergen Drug Corporation (ABDC) as a prime vendor and procure a majority of its product purchases from ABDC. In return, the pharmacy would pay a fee to get all the support services to run the store effectively. Looking at the attrition of the independent pharmacies in the early 1990s most should have been out of business by now. But independent pharmacies are a thriving business, serving many rural communities in the U.S., because of the wholesalers' support services.[49] There are about 2,800 pharmacies that are part of the GNP network out of about 30,000 independent pharmacies in the U.S.

The cooperation between the wholesaler and independent pharmacies is common in the industry and gives the pharmacy owner a national store-brand identify.[50] Given my research in the area of franchising, this model works well and very efficient for both the wholesaler and the pharmacies.[51]

3. Wholesale Lack Market Power

Figure 3 illustrates the distribution of $100.00 across various channel members in the supply chain. The wholesaler share is about $1.00 for the supply of branded drugs. Importantly, more than 80% of prescription drugs distributed by the wholesalers (by value) are branded drugs. For the generics, the wholesaler share is approximately $8.00 out of the $100.00 generic product distribution. The

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R., T., Jambulingam, *Drug Wholesalers and Their Customers, Attitudes and Expectations on Current and Future Service and Integration*, NWDA Report (Aug. 1999).

[49] In the 1990s, I developed a simple projection model to estimate the extinction of independent pharmacies based on the rate of closures and acquisitions of independent pharmacies. My estimate was by early 2000s the independents should have been extinct given the rate of decline. In the last 18 years, however, the independent pharmacies not only thrived, but are doing especially well in rural communities where chain pharmacies do not go in because of the population size. This is due the cooperative partnership between the wholesaler and pharmacies, which ultimately benefits many patients.

[50] Similar to ABDC's GNP, McKesson has Health Mart, Cardinal has Medicine Shoppe/Medigap pharmacy loyalty programs.

[51] Jambulingham, T., Nevin, J.R., *Influence of Franchisee Selection Criteria on Outcomes Desired by the Franchisor*, 14 J. Bus. Venturing (1999), 363-395.

margins indicate that the wholesalers are the least powerful in demanding a higher share of revenue in the supply chain.

Figure 3: Distribution of $100.00 Across Various Channel Members in the Supply Chain[52]

Channel Member	Branded Drugs (Distribution of $100)	Generic Drugs (Distribution of $100)
Manufacturer	$76	$36
Wholesaler	$1	$8
Pharmacy	$3	$32
PBMs	$2	$7
Insurer	$19	$17

4. ABDC' Profit Margin is less than 3%

Analyzing ABDC's financials from 2007 to 2018, the average gross margin is 2.8% and net profit is 0.64%,[53] which indicates that ABDC operates at a razor thin margin and is an extremely efficient contributor in the supply chain. (*See* Figure 4 below). For ABDC, from 2008 to 2011, 100% of the revenue was from distribution. From 2011 to 2018, the average share of the distribution revenue was 97.5%.[54]

[52] Shih, T., Sood, N., Van Nuys, T., Goldman, D., *The Flow of Money Through the Pharmaceutical Distribution System*, USC Schaeffer Center for Health Policy and Economics (Jun. 13, 2017). Another study estimates the wholesaler share as $0.50. PhRMA, *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*, 10 (Nov. 2017) http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.

[53] FactSet Data Analysis for ABC from 2007-2018. A screenshot of the relevant data from this database is attached hereto as Appendix C.

[54] *See id.*

Figure 4: ABDC Financials 2007 - 2018[55]

ABC Financials	Sep 07	Sep 08	Sep 09	Sep 10	Sep 11	Sep 12	Sep 13	Sep 14	Sep 15	Sep 16	Sep 17	Sep 18	AVERAGE
Sales in $ Billions	66.07	70.19	71.76	77.95	80.22	79.49	87.96	119.57	135.96	146.85	153.14	167.94	104.8
Gross Income	2.2	1.95	2.02	2.25	2.43	2.51	2.32	2.77	3.22	3.77	4.15	4.11	2.8
Gross Margin (%)	3.33	2.78	2.81	2.89	3.03	3.16	2.64	2.32	2.37	2.57	2.71	2.45	2.8
Net Income	0.49	0.47	0.51	0.64	0.71	0.71	0.49	0.28	-0.13	1.43	0.36	1.66	0.64
Net Margin (%)	0.75	0.67	0.71	0.82	0.88	0.89	0.56	0.24	-0.10	0.97	0.24	0.99	0.64

In his yearly report, Dr. Adam Fein—an expert in supply chain economics from Pembroke Consulting—shows the buy side margin is about 12.87% and the sell side margin is -9.63% leading to an overall margin of 3.24%.[56] (*See* Figure 5 below).

Buy side revenue is created due to distribution service agreements or fee for service agreements, volume discounts, stocking allowances, rebates and other payments and prompt pay discounts. The sell side margins are negative because of the pass-through rebates to the customers netting an overall lower margin of 3.24%. As a comparison, the average gross margin at all U.S. merchants' wholesalers of nondurable goods from 2007-2017 was 13.35%[57] much higher than the pharmaceutical wholesaler margins.

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[55] *See id.*

[56] Fein, Adam J., Ph.D. *The 2017-2018 Economic Report on Pharmaceutical Wholesaler and Specialty Distributors*, Drug Channels Institute, 91 (2017).

[57] U.S. Census Bureau, *The 2019 Annual Wholesale Trade Report*, (2019).

Fig. 5: Estimated Buy-Side and Sell-Side Contributions to Wholesalers' Gross Margin, 2017

	Brand-Name Drugs[3]									
Product Type: Percentage of Revenues:	Top 6 Pharmacies[4] 41%		Smaller Pharmacies 20%		Healthcare Providers[5] 23%		Genetic Drugs[6] 16%		Total 100%	
	Base Points	% of Buy-Side GM	Base Points	% of Buy-Side GM	Base Points	% of Buy-Side GM	Base Points	% of Buy-Side GM	Base Points	% of Buy-Side GM
Buy-side gross margin components										
Distribution Service Agreements[1]	295	56%	295	56%	295	56%	1,050	20%	417	32%
Volume discounts, stocking allowances, rebates, & other payments	35	7%	35	7%	35	7%	4,000	76%	670	52%
Prompt Payment Discount	200	38%	200	38%	200	38%	200	4%	201	16%
Buy-side gross margin (total)	530	100%	530	100%	530	100%	5,250	100%	1,287	100%
Sell-side margin	-470		-385		-400		-3,750		-963	
Total Gross Margin (basis points)[2]	60		145		130		1,500		324	

Basis Point = one hundredth of one percent (0.01%); GM = Growth Margin

1. Figure reflects weighted average of small and large manufactures. Includes the net value of allowable inventory revaluation (where applicable)
2. These figures represent an industry average model for the Big Three pharmaceutical wholesalers. Any individual company's performance will vary based on sales mix, client mix, and other factors.
3. Includes traditional and specialty brand-name drugs.
4. Includes brand-name sales to six largest wholesaler customers: CVS Health; Express Scripts; OptumRx; Rite Aid; Walgreens Boots Alliance; and Walmart.
5. Includes hospitals, health systems, physician offices, clinics, and other non-retail healthcare providers.
6. Figures are not comparable to previous reports' presentations. See text for details.

Source: Pembroke Consulting Estimates. Totals may not sum due to rounding.

5. Wholesalers' role in Trade Promotions

In the U.S., about 90% of all sales of prescription pharmaceuticals are brands. With respect to the number of prescriptions, 90% of the prescriptions dispensed are for generics. For the brands, wholesalers do not have the market power as indicated by total gross margins. (*See* Figure 5). Given the intense competition between the large wholesalers to retain their market share they participate in the trade promotions with the branded manufacturers. For the generics, which is 10% of dollar value but 90% of the prescriptions, intense competition among manufacturers to obtain or retain market access for their products provides wholesalers market power.

The wholesalers negotiate better contracts or trade promotion deals with the manufacturers, but the competitive nature of the wholesale business requires they provide pass-through rebates to keep the downstream customers leading to negative sell side margins. (*See* Figure 5). For example, there are 20 different manufacturers all have the generic versions of Fentanyl. When generics are approved by the FDA, they are given a rating as to what extent the product is bioequivalent to the

brand. If a product receives an "AB" rating then the product is considered bioequivalent to the brand. Almost all Fentanyl products are AB rated. Given the lack of differentiation, the manufactures use price to compete in the market. The wholesalers use the generic sourcing program and they would only contract with one or two manufacturers from the 20 manufacturers to be included in the Generic Source Program based on price. Part of the savings goes the pharmacies as a pass-through rebates.[58]

In forming my opinions in this case, I have reviewed a number of the statement of work documents from ABDC.[59] My opinion to a reasonable degree of professional certainty is that these documents contain common trade promotion terms, which are not unique to any product. For example, many of the statements of work contain language indicating that ABDC does not endorse the manufacturer's content:

> Manufacturer acknowledges that Company makes no representation, warranties, or endorsements regarding the quality, accuracy or reliability of any information (including without limitation, the information), data graphics or other content of any kind posted on or contained in the Service (collectively, "Content"). Company has on obligation to review any Content or to remove any Content.[60]

Importantly, with respect to demand creation for opioids, the wholesaler has the least power since the physicians, payers, and pharmacists control the prescribing, reimbursement and dispensing of opioids. In addition, consistent to the CSA requirements wholesalers report all the opioid sales to the DEA, which information is then stored in the ARCOS database.

In summary, the wholesalers are the least profitable supply chain member with the most efficient operations. The margins also indicate that they cannot demand more share of the dollar revenue because they do not have the power in the system. The low margins require the wholesaler to work closely with the supplier (manufacturers) and buyers (pharmacies) by integrating the business processes to achieve efficiency.

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[58] Pass through margin is when the wholesaler get a margin or profit from the buy side of the transaction with the manufacturer and they share that margin with the pharmacy leading to reduced cost of acquisition of the product for the pharmacy.

[59] ABDCMDL00375564; ABDCMDL00375580; ABDCMDL00375582 - ABDCMDL00375584; ABDCMDL00375598; ABDCMDL00375631; ABDCMDL00375640; ABDCMDL00375641; ABDCMDL00375642 ABDCMDL00375643;ABDCMDL00375644; ABDCMDL00375646; ABDCMDL00375649; ABDCMDL00375654 -ABDCMDL00375657ABDCMDL00375660; ABDCMDL00375663 - ABDCMDL00375668; ABDCMDL00375671 ABDCMDL00375676 - ABDCMDL00375683 - ABDCMDL00375688; ABDCMDL00375696; ABDCMDL00375707 - ABDCMDL00375712 - ABDCMDL00375715 - ABDCMDL00375718; ABDCMDL00375723 -01837025; MNK-T1_0000510177; MNK-T1_0006659403; MNK-T1_0006661796; MNK-T1_0006661806; MNK-T1_0006661807; MNK-T1_0006664418; MNK-T1_0007260134; MNK-T1_0007729166; MNK-T1_0007832541; PPLP004397425; PPLP004397461; PPLPC022000986873; PPLPC022000986875.

[60] ABC-MSAGC00002143.

E. Wholesaler and Pharmacies are Different Class of Trade

Wholesaling and pharmacies are two separate businesses. Wholesalers distribute a wider variety of products (about 55,000 SKUs) including branded and generic pharmaceutical products, OTC products, home health supplies and medical equipment to the pharmacy customers.

Wholesaler	**Pharmacies**
Do not interface with patients	Interface with patients and counsel them
Do not have the authority for therapeutic or generic substitution	Have authority for therapeutic and generic substitution
Primarily do not communicate with physician on therapeutic decisions	Regularly communicate with physicians on therapeutic decisions
Do not have the license to dispense medications to the patients	Are licensed to dispense medications to the patients
Wholesalers are a different class of trade and one step removed from the end user interface with the patient	Pharmacies are a different class of trade from the wholesaler and they are the end user interface for the patients
Less or no influence in what brand is filled in the prescription	Pharmacists have more influence on what brand is filled specially if a therapeutic substitution option exists

F. Opinions Related to Plaintiffs' Expert Reports

1. Mathew Perri III, PhD

In his expert report, Dr. Perri provided a description about the role of marketing in the pharmaceutical industry specific from the manufacturer's perspective. Importantly, Perri fails to clarify that the wholesalers, in general, do not commercialize products as they are in the service business. Wholesalers provide a logistics service for efficient movement of products in the supply chain.

Instead of the 4 Ps for marketing a product, the wholesalers, who are in the service business, have 7 Ps, Product, Place, Promotion, Price, People, Process and Physical Evidence. The product is the service the wholesalers provide to physically move the product from the manufacturer, store the product in the warehouses, and safely deliver the product to the pharmacies and other outlets. The place is the type of warehouses wholesalers would locate to transfer the product, and store them with high levels of security, closer to the customer. Wholesalers promote their services to the manufacturers and the pharmacies (refer to the list of services I discussed earlier, including ability to deliver product in small shipments in a timely manner). The next "P" is price. Wholesalers charge service or access fees for all the services they provide using a fee for service model. For example, if the manufacturer wanted new product launch support for a branded drug, it would need its product to be made available to the pharmacies, REMS support, and possibly support

distributing information to the pharmacies, such as price, availability, and quality.[61] Wholesalers would provide these services to the manufacturer for a fee, which is part of the contract.[62]

With respect to generics manufacturer, the wholesalers adopt a different approach. Generics are multiple source products with many different suppliers or manufacturers of the product. The products are mostly identical with an "AB" rating from the FDA. The only way for each one of the generic products to compete for market share is get access to the supply chain. Given that all the generics for a brand have a similar FDA rating, they compete on price to access the supply channel. The wholesaler can negotiate better prices for generics than for the branded products, but the wholesaler has to pass-through the margins to the pharmacies because of competition. (*See* Figure 5 related to the sell side margin for generics). The intense competition among wholesalers can drive the prices down because of the pass-through margins.[63]

Dr. Perri's opinion that distributors were integral to selling Kadian because they could select the generic offering the best pricing and availability to use in their generic source programs needs clarification. While it is possible that the sale of Kadian, through the generic sourcing program, could increase the share of the Kadian generic. The share of Kadian within the class (generic, controlled substance) as a proportion could go up, but the total quantity within that class of products will remain the same because the physician still has to write the prescription for the product. This suggests that the pricing incentives did not increase the volume of opioids overall within the class, it simply shifted which opioids were being purchased.

The other three "P"s for the service industry are People, Process, and Physical evidence. Wholesalers rely on employees to provide excellent service to meet the needs of the customers. They excel the supply chain processes to integrate operations for efficiency and have state of art technology-based facilities as physical evidence for the capabilities to run an efficient, responsive and compliant operations by meeting both the regulatory and business requirements.

Given my supply chain expertise and understanding of the economics of the supply chain, every stakeholder should add value to the supply chain or else they will be eliminated or disintermediated. With more than 52,000 stock keeping units (SKUs) or products that differ by types, such as prescription (small molecules, biologics, generics, biosimilars), OTCs, health and beauty aids, devices, etc., as well as dosages forms (tablets, capsules, injectables, topicals, etc.), storage requirements (ambient, cold chain etc.), and regulatory compliance requirements (scheduled and non-scheduled), delivering life-saving products to the right patient/customer, at the right quantity, and at the right time is the key responsibility of all in the supply chain. Since the wholesaler is the middleman in the process they play a vital role.

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[61] Dep. of Matthew Perri, III, April 24, 2019, at 198.

[62] Because the services can be easily copied by competitors leading to price competition, the wholesalers may have to pass on the profit margins they make with the manufacturer to the pharmacies (*see* Fig. 5).

[63] The payer reimburses pharmacy for generic drugs based on maximum allowable cost (MAC). MAC is a cost management program that sets the upper limits on the unit price that will be paid for equivalent generic drugs available from different generic manufacturers. The payers (Medicaid and Private Third Party) use MAC lists to control costs of generics reimbursement. As the prices drop, the reimbursement based on MAC by the payers decreases too and the pharmacy will continue to look for cheaper prices to remain profitable.

In my opinion to a reasonable degree of professional certainty, Dr. Perri's conclusion that the wholesaler is involved in jointly marketing opioids with the manufacturers is incorrect.[64] The manufacturers, wholesalers, and pharmacies are different classes of trade. Dr. Perri's report failed to distinguish these different roles and instead lumps them together as a group. After reviewing all the "Statement of Work" and "Distribution Agreements," it is my opinion that none of those documents indicate "joint marketing" for profit motive, but rather "jointly planning" and facilitating the manufacturer's trade promotions to the pharmacy customers.

Further, Dr. Perri opines that the sole reason for the coordination between the members in the supply chain is to optimize revenue flow. Throughout my report, I draw several key distinctions on the role each play in the supply chain and emphasize some below.

First, pharmaceutical manufacturers, wholesalers and pharmacies have distinct roles in the supply chain. Pharmaceutical manufacturers develop and market the drugs, the wholesalers provide logistical support to distribute the drug, and the pharmacy dispenses the drug to the patient. Second, the coordination the supply chain is to create efficiency and responsive system to meet the needs of the patients. Third, the profit margins among the three entities are vastly disparate. With respect to the brands, the manufacturer gets the major share of the revenue (76%) as opposed the wholesaler (1%). The low margins are due to the wholesalers' lack of power to demand higher shares of the revenue. Finally, there are several factors such as regulatory compliance, drug security, disaster planning, recalls, and chargeback negotiation among others that require channel coordination and planning and not just revenue maximizing. With respect to ABDC, the coordination is achieved by process integration with different customer groups and not ownership based.

Dr. Perri, in his deposition, makes a generic statement that the "vast majority of opioid utilization was caused by marketing message." The statement is vague and unsupported, especially in the context of wholesalers. In general, manufacturers can use different channels to send messages about their products, including physician directed (through the use of sales representatives, journal advertising, and meeting and events, etc.), patient directed (through the use of direct to consumer advertising, and coupons etc.), as well as payer directed (through the use of sales reps, pharmacoeconomic studies, rebates for formulary placements, risk sharing programs etc., or trade promotion to pharmacies). Dr. Perri did not conduct any quantitative analysis to determine whether defendants' marketing influenced any prescribing decision. Rather, he opined that it did based on a qualitative observation that prescriptions rose rapidly at the same time defendants increased marketing/promotional efforts. He described his report as a "qualitative report." Importantly, this conclusion is unsupported as an observational correlation is not causation.

In paragraph 93 of his report, Dr. Perri states the following: "Manufacturers submit advertising materials to the FDA's Office of Prescription Drug Promotion (OPDP), but FDA approval prior to dissemination is not required. Thus, inaccurate or unbalanced advertisement may be in circulation until the FDA identifies them. The FDA can intervene by way of a warning letter for advertising materials that it finds do not accurately convey a drug's labeling. FDA's oversight of advertising

[64] Dep. of Matthew Perri, III, April 25, 2019, at 152.

can be delayed, allowing improper advertising materials to reach a large audience before being pulled back."

While the OPDP does not require manufacturers to submit advertising material prior to dissemination, a majority of the companies do, in fact, submit these materials for FDA review and approval. Dr. Perri's report assumes that companies deliberately create inaccurate or unbalanced advertisements banking on the fact that FDA may not identify them. In my expert opinion, this is not the case. Rather, companies train their brand team and outside advertising agencies and provide rigorous review conducted by the internal compliance teams to make sure the advertising material is accurate before dissemination.

Dr. Perri testified that he did not make any determinations about whether the marketing claims were false or misleading, but was relying on other experts and the FDA warning letters. However, Dr. Perri failed to note that the issuance of a warning letter is catastrophic for a companies' revenue. Specifically, in a study that I conducted on the financial impact of warning letters of pharmaceutical companies, I concluded that the loss of value was significant. For instance, on April 2, 2009, eleven pharmaceutical companies received warning letters for violation of presenting risk information, I estimated using the abnormal returns, the loss of value over the 3-day period after the warning letters was equivalent to a market capitalization loss of $18.4 billion for the eleven companies.[65]

Consequently, pharmaceutical companies do take developing the promotional material according to the label seriously. Moreover, many violations are reported by competitors, not simply the FDA, which supports the idea of market-based self-regulation. In the study I conducted, the key reason for the violation was that the sponsored link had inadequate risk information. This is due to limited number of characters available in each ad. For example, Google had room for only 95 characters, including the headline. This was a technology barrier created by Google. But until May of 2009, the FDA did not have clear guidelines for the use of online technologies such as search engines. With the lack of guidelines or advice from FDA, the companies were not sure what constituted compliance. In May of 2009, (*after* issuing the warning letters), DHHS along with several organizations, including FDA, released its first draft guidance document (not final) to provide initial guidance on promotion online.[66]

I reviewed a number of FDA warning letters in preparing my report.[67] None of these letters supports Dr. Perri's conclusion that the marketing materials generated by pharmaceutical

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[65] Jambulingam, T., Sharma, R., *Estimating the Value of Internet Marketing in the US Pharmaceutical Industry*, 10 J. Med. Mark (2010), 332-343.

[66] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), Center for Devices and Radiological Health (CDRH), *Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion, Draft Guidance* (May 2009) https://www.fda.gov/media/76269/download.

[67] ALLERGAN_MDL_00638086, PDD9316710173; Janssen Duragesic warning letter; 11/9/2001, Ortho McNeil Nuncynta IR warning letter; Pfizer Avinza warning letter; 3/30/2009, Purdue MS Contin warning letter; 5/11/2000; Purdue Oxycontin warning letter; 3/24/2008, Purdue Oxycontin warning letter; 3/26/2009; Purdue

manufacturers were all fraudulent or misleading. For example, the drug at issue in the Boehringer Ingelheim Roxane Inc. Roxanol & Roxicodone warning letter from 3/30/2009 was marketed for many years before the letter was sent in 2009 by the office of compliance (not OPDP) to bring it under approval using the FDA's unapproved drugs initiative—***not for advertising or marketing violations***.[68] This was an effort made by the FDA to proactively assist companies to find ways to legally market products that were currently marketed without the required FDA approval. The products underwent the required approval by FDA and entered the market.[69]

Four other products cited by Dr. Perri in his report received untitled letter and not warning letters.[70] As mentioned above, an Untitled Letter cites violations that do not meet the threshold for regulatory significance. Therefore, the format and content of an Untitled Letter should clearly distinguish it from a Warning Letter. The characteristics of an untitled letter, include (1) the letter is not titled; (2) the letter does not include a statement that FDA will advise other federal agencies of the issuance of the letter; (3) the letter does not include a warning statement that failure to take prompt correction may result in enforcement action; (4) the letter does not evoke a mandated follow-up; and (5) the letter requests (rather than requires) a written response from the firm within a reasonable amount of time.

For example, Cephalon's Fentora received an untitled letter that was issued on April 4, 2009, which stated that the "sponsored links on internet search engines (e.g., Google.com) for the following products FENTORA (fentanyl buccal tablets) (Fentora), and TREANDA (bendamustine hydrochloride) for Injection (Treanda) are misleading because they make representations and/or suggestions about the efficacy of Fentora and Treanda, but fail to communicate any risk information associated with the use of these drugs."[71] As I explained earlier, the technology limitations caused by Google and the lack of clear guidelines lead to the problem, not the actual marketing material. This is a classic scenario where the FDA is learning and regulating promotion at the same time. This poses challenges to the companies with respect to compliance and can result in the receipt of warning letters or untiled letters.

The FDA frequently learns while regulating. As I mentioned above, in 1998, the FDA issued 7 warning letters and 151 untiled letters for a total of 158. In 2018, FDA issued 2 warning letters and 5 untitled letters for a total of 7 letters, a precipitous drop or reduction in violations. This illustrates that in 1998, right after allowing direct to consumer advertising by the FDA in 1997, the

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Pharma warning letter; 10/08/2009, Roxane warning letter; 8/26/2011, Watson warning letter; 1/17/2003). Although cited in Perri's materials reviewed, I searched through the all the letters issued by OPDP from 1998 to date, but was unable to find the following warning letters: 3/24/2008 Purdue Oxycontin warning letter, 3/26/2009 Purdue Oxycontin warning letter, and 10/08/2009 Purdue Pharma warning letter.

[68] Dr. Perri indicated this letter was from 3/15/2010, but the correct date appears to be 3/30/2009.

[69] Institute for Safe Medication Practices, *FDA Advise-EER: A New Look for Morphine Sulfate 100 mg per 5 mL (20 mg/mL) Oral Solution* (Feb. 11. 2010), https://www.ismp.org/resources/fda-advise-err-new-look-morphine-sulfate-100-mg-5-ml-20-mgml-oral-solution.

[70] They are: (1) Cephalon Fentora warning letter, 5/12/2009 (correct date is 4/3/2009), (2) Janssen Duragesic warning letter; 11/9/2001 (correct date – 3/30/2000), (3) Ortho-McNeil Nuncynta IR warning letter- the date is 8/26/2011 and Watson warning letter; 1/17/2003– correct date (10/23/2000).

[71] FDA Untitled Letter, Cephalon's Fentora, (Apr. 4, 2009).

industry did not know what is considered violation and received an all-time high of 158 letters. Overtime with the FDA providing better guidelines to promotion the pharmaceutical industry has promote responsibly to improve health of the society.

In summary, there are several contradictions in the analysis and assumptions made by Dr. Perri with respect to the distinct role of wholesalers as a logistics partner and limited power in the supply chain. As such, I disagree with Dr. Perri's opinions concerning the wholesalers' role, and specifically ABDC's role, with regard to marketing opioid products.

2. David Egilman, MD

In my opinion, all of Dr. Egilman's opinions related to wholesalers, and ABDC in particular, are unsupported by the documentation. In fact, Dr. Egilman's references to coordinated activities for illicit purposes, actually describe required coordinated activities to help patients and operate within the law. In my opinion, to a reasonable degree of professional certainty, Dr. Egilman's references to misleading marketing activities by wholesalers show nothing misleading at all. Rather, the communications are typical business correspondence in an effort to convey administrative information about products, such as quality, price, and availability. I simply cannot follow the logic, if any, that manufacturers were in some way "connected at the hip" with wholesalers. (*See* Egilman Exhibit B.336). Rather, wholesalers are always trying to find ways to improve the efficiency of the supply chain and attending meetings is a standard business practice to learn about opportunities to do just that and also keep abreast of changing regulatory landscape.

Further, after reviewing Egilman's cited materials, I disagree that wholesalers were a conduit for misinformation to pharmacies. I also disagree that wholesalers had the capacity to monitor use and failed to do so. Egilman's cited evidence simply does not support these conclusions.

For instance, Dr. Egilman opines in his report under exhibit B.109, that the "manufacturer used wholesalers as conduit for marketing." In support of that statement, Dr. Egilman cites a memo that was sent by Sheldon Benson from Purdue Pharma to Steve Said at Mckesson concerning different promotional tools, such as RxBulletin, FaxBlast, E.Video and an educational program for pharmacists to launch their newly reformulated (abuse deterrent formulation (ADF)) oxycontin. In addition, Purdue had launched RxPATROL (Rx Pattern Analysis Tracking Robberies & Other Losses) to deter crime such as theft and burglary in the pharmacies through a web-based information clearinghouse and wanted to educate pharmacist about the program.[72] In my opinion to a reasonable degree of professional certainty, the use of the above-mentioned communication channels to create awareness of a new product to licensed healthcare professionals, such as a pharmacist, is a standard communication in the industry. Pharmacists need to know about new products so that they can be prepared if a physician or patient requests information. Also, when new product launches occur, pharmacies should carry a box of the product, at minimum, in case

[72] In fact, Dr. Egilman refers to the promotion of RxPATROL® (Pattern Analysis Tracking Robberies and Other Losses), which is an initiative designed to collect, collate, analyze and disseminate pharmacy theft intelligence to law enforcement throughout the nation. I see no correlation to the promotion of an anti-theft system and any of Dr. Egilman's opinions.

they need to fill a prescription. Similar use of communication channels is used in many other industries and for other pharmaceutical and OTC products.

Dr. Egilman also opined that "Purdue used wholesalers and retailers to market opioids." See Egilman Exhibit B.188. In support of this conclusion, he cites the distribution strategy document of Hysingla ER with launch timeline, specifics about trade promotion details, such as stocking goals for wholesalers, pharmacies, and incentives for wholesalers to pharmacies. Once again, this is a standard process to have a new product available in the pharmacies before the drug launch. Hysingla ER was approved in the U.S. on November 20, 2014 as an extended release, once-daily hydrocodone product with abuse-deterrent properties.[73] It is a standard practice in the industry to have the drug available at the pharmacy before the pharmaceutical representatives promote the product.

Further, the wholesalers on an average distribute about 52,000 products including prescription, OTCs, and other health related products. The wholesaler would set an access fee as part of the distribution services agreement for the manufacturer to communicate the availability of the product to the pharmacies. The wholesalers channel the manufacturers' information about the product, price, availability and quality to the pharmacies. Moreover, the information is passed on only to customers of the wholesaler (pharmacies), not prescribers or patients. The pharmacies can decide to stock or not stock the product. As per the distribution strategy document[74] pharmacies can return the product back within a year back to the manufacturer if they do not want to carry the stock. As I discussed earlier in the document, the demand for the product dependent upon the physicians prescribing the product, patients decide to fill the prescription payer paying for the product and the pharmacist filling the prescription for the product. The wholesaler does not have any control in determining the demand of what drug and how much gets filled in the market.

With regard to Dr. Egilman's opinion that ABDC wanted to hide its association with the Pain Care Forum (Egilman Exhibit B.121), I disagree that the term "Low key" is a term that is used by business people as an "informal" meeting. It has nothing to do with hiding things. Without knowing more details I cannot comment on this assumptions/intentions made in this comment. The Pain Care Forum is co-founded by Bert Rosen, a Purdue Pharma Executive. The Pain Care Forum's members include Pharmaceutical, Medical Device companies, Pain foundations and associations etc.[75] I do not know what Dr. Egilman is alluding to there. Finally, based on Rita Norton's deposition, ABDC did not join the Pain Care Forum.

Finally, in the last 10 years with the advent of Affordable Care Act, the competitive landscape in the healthcare industries is changing rapidly. There are increased consolidations *via* mergers, acquisitions, and alliances in the industry to improve efficiencies and reduce uncertainty and risk. Insurers, PBMs, provider practices, hospitals, manufacturers, and pharmacies are merging both within their class of trade and also creating an integrated healthcare industry. The wholesalers are

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[73] U.S. Food & Drug Administration, *Hysingla ER (hydrocodone bitartrate) Extended-Release Tablets*, (Apr. 4, 2015) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206627Orig1s000TOC.cfm.

[74] PPLPC025000171067

[75] Shaw, Solana, *Pain Care Forum Directory*, (Apr. 2012) https://assets.documentcloud.org/documents/3108980/PAIN-CARE-FORUM-Directory-04-2012.pdf.

undergoing the transformation as well. In 1929, there were more than 1,200 drug wholesalers in U.S. The low margins due lack of negotiation power with brand manufacturer, declining profitability with the generics because of price competition, increasing supply chain regulations and compliance costs, consolidation in the pharmacy business, and slowing down in the growth of healthcare spending in U.S., have put significant price pressures on the wholesalers.[76] In order to deal with the changing business needs, ABDC has forged a strategic long-term relationship announcement with Walgreens and Alliance Boots GmBH to streamline distribution of pharmaceuticals to Walgreen stores (up until that time Walgreens had their own warehouse and distributing internally to their stores). In addition, another objective of the partnership is to leverage global supply chain efficiencies and improve access the medicines to patients. The contract is a ten-year distribution contract whereby Walgreens and Alliance Boots were given equity stake of 26% of ABDC. Recently, ABDC announced that Walgreens stake in ABDC will not go past 30% which will keep Walgreens and Boots Alliance a minority equity holder in ABDC. In my opinion, this is a strategic business decision that will free up some operating costs and help to keep up with the competition. In my opinion, to a reasonable degree of professional certainty, this is just one example of a move surrounding the general shift to vertical integration in the marketplace, it is not evidence of collusion as Dr. Egilman suggests (*see* Egilman Exhibit B.377).

VII. CONCLUSION

In conclusion, wholesalers, like ABDC, are efficient logistics companies that play a vital role in the supply chain for pharmaceuticals. The competition among the wholesalers is fierce and has driven their profit margins to low single digits, which is a benefit to society. For the generics, the wholesaler uses generic sourcing programs to negotiate prices with the manufacturers, but the competition for pharmacy customers forces the wholesalers to share their margins with the pharmacies leading to razor thin profits.

Wholesalers do not have the authority to change or modify the label of a pharmaceutical product nor do they have the competency or ability to access compliance of manufacturers for promotional regulations. It is the FDA that is challenged with regulating the promotions for pharmaceuticals, the wholesalers are not in any position to make those determinations. Wholesalers are simply a channel through which manufacturers conduct their trade promotions to the pharmacies, especially brands. Generics go through the wholesaler's generic sourcing program and bring value to the pharmacies by improving their acquisition costs. The majority of those programs communicate information about the product's price, availability and quality.

[76] Beckman, Theodore N., *Changes in Wholesaling since 1929*, National Marketing Review, Vol. 1, No. 1 (Summer, 1935), 39-48, https://www.jstor.org/stable/4291275.

New regulations or guidelines are constantly introduced and existing regulations or guidelines are modified by the FDA, DHHS, DEA, CMS, State Boards of Pharmacy, and other agencies, leading to complexity and high cost of compliance. The close working relationship or coordination of the wholesaler with the manufacturer and the pharmacy ensures compliance and public safety. The coordination is not evidence of some type of "collusion" or "joint at the hip" activities with sinister objectives.

Respectfully submitted,

Thani Jambulingam Ph.D.
Date: May 10, 2019

Appendix A

Materials Reviewed & Considered

DR. THANI JAMBULINGAM – MATERIALS REVIEWED AND CONSIDERED

Court Documents
Cuyahoga County Second Amended Complaint
Summit County Second Amended Complaint
Cleveland Second Amended Complaint
Summit County Third Amended Complaint

Depositions
Rough transcript from the deposition of Dr. Matthew Perri (4.23.2019 & 4.24.2019)
Rough transcript from the deposition of Dr. David Egilman (4.26.2019 & 4.25.2019)
Transcript and exhibits from the deposition of Celia Weber, 1.25.2019
Transcript and exhibits from the deposition of Bruce Gundy, 2018.11.07
Transcript and exhibits from the deposition of Chris Zimmerman, 2019.02.08
Transcript and exhibits from the deposition of Chris Zimmerman, 2018.08.03
Transcript and exhibits from the deposition of David May, 2018.08.04
Transcript and exhibits from the deposition of Edward Hazewski, 2018.10.25
Transcript and exhibits from the deposition of Elizabeth Garcia, 2018.12.14
Transcript and exhibits from the deposition of Eric Cherveny, 2018.11.09
Transcript and exhibits from the deposition of Gabriel Weissman, 2019.01.17
Transcript and exhibits from the deposition of Kevin Kreutzer, 2018.11.27
Transcript and exhibits from the deposition of Nathan Elkins, 2018.11.14
Transcript and exhibits from the deposition of Nikki Seckinger, 2018.12.12
Transcript and exhibits from the deposition of Rita Norton, 2019.01.09
Transcript and exhibits from the deposition of Sharon Hartman, 2018.11.29
Transcript and exhibits from the deposition of Steve Mays, 2019.02.08
Transcript and exhibits from the deposition of Stephen Mays, 2018.10.24

Plaintiffs' Expert Reports
3.25.2019 Report of Dr. David Egilman
3.25.2019 Report of Dr. Jane Ballantyne
3.25.2019 Report of Dr. Matthew Perri
3.25.2019 Report of Dr. Theodore Parran
3.25.2019 Report of Dr. Mark Schumacher

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PPLP004397601
PPLPC022000986873
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Appendix B

Curriculum Vitae Dr. Thani Jambulingam

Thani Jambulingam, Ph.D.
Professor, Arrupe Research Fellow
Pharmaceutical and Healthcare Marketing
Saint Joseph's University
tjambuli@sju.edu

Professional Interests

Research Interests

Pharmaceutical Marketing Strategy, Regulatory Economics, & Supply Chain Management

Teaching Interests

Pharmaceutical Marketing Strategy, Supply Chain Management and Competitive Analysis

Academic Background

Ph.D. University of Wisconsin, Madison, Wisconsin, Pharmacy Administration 2001
M.S. University of Wisconsin, Madison, Wisconsin, Pharmacy Administration, 1995
M.S. Birla Institute of Technology, Ranchi, India, Pharmaceutical Technology, 1989
B.S. University of Madras, Madras, India, Bachelor of Pharmacy, 1985

Academic Experience

2016 – Now Professor, Department of Pharmaceutical and Healthcare Marketing
2012-2016 Associate Professor, Department of Pharmaceutical and Healthcare Marketing
2011-2012 Pfizer Fellowship, Prevnar Global Commercial Team, Pfizer Inc. Collegeville PA
2003-2010 Department Chair and Associate Professor
1998- 2003 Assistant Professor, Department of Pharmaceutical and Healthcare Marketing

Research Accomplishments

Consistent with my overall philosophy of pragmatism, my research focus has been what I perceive to be the compelling need of the pharmaceutical and healthcare industry— organizational structure and conduct and its impacts the performance of the pharmaceutical firms in a regulated environment. Specifically, I have been examining the notion of organizational structure as strategic choices (alliances, mergers and acquisitions), organizational conduct (entrepreneurial orientation, diffusion of innovation, inter-organizational relationships), and impact of regulations on organizational performance using theories in marketing, management and economics.

I have a pharmacy background, and have worked in the pharmaceutical industry in sales and in product management launching products for large pharma companies and have served as a consultant to the industry. In 2011-2012 as part of my sabbatical experience, I launched a vaccine globally for Pfizer as part of the global commercial team. I am cognizant of the needs of managers

and the challenges that they face in improving performance and gaining a competitive edge. I, therefore, engage in "meaningful" research that involves both the development and testing of models. I have developed some complex, but interesting, conceptual as well as analytical models, and tested them by using a combination of quantitative and qualitative research methodologies.

Industry issues are multifaceted and multidisciplinary in nature, hence I seek frameworks from multiple disciplines such as marketing, management, operations, finance, accounting using industrial organization framework to conduct research and identify solution that are related to the industry. If you look at the co-authors you can see the diversity of disciplines which I enriched myself but also able to provide insights to them. My desire to find solutions to managerial problems not only helps me in keeping abreast of new developments in the field, but it also enables me to deliver state-of-the-art knowledge to my students through continuously updated teaching material. My research work has so far yielded **23** refereed publications in academic journals, an industry report, one case study, **9** refereed conference proceedings, and **23** conference presentations, and **14** invited pharmaceutical and healthcare industry specific non-referred conferences. The industry conferences provide impetus to my research and also teaching in my courses.

I have held the rank of Associate Professor since Fall of 2003. During this time, I have seven articles (P15-P9) published in refereed academic journals that follow a double-blind review process and are highly selective. Two of these seven papers are in the highest ranked journal in my field namely International Journal of Pharmaceutical and Healthcare Marketing (IJPHCM). In addition, I have one paper revise and resubmit (PR1) at IJPHCM and three papers nearly ready for submission to journals. Post tenure, I have made 18 refereed presentations at regional, national and international academic conferences of which 9 appeared in refereed conference proceedings. Since 2003 I also served as the chair of the department teaching 12 credits, serving 6 committees in a teaching intensive school with no PhD program. I have been instrumental in launching an online program in pharmaceutical and healthcare MBA, integrating off-line and on-line MBA programs and developing new curriculum in the changing healthcare space and managing three different programs.

Honors and Awards

My research activity has been recognized both within and outside of my employer institutions. In 2009 the paper I published in the International Journal of Pharmaceutical and Healthcare Marketing received the "Highly Commended Paper Award" by the publisher. In 2007 my paper received the best paper award in the marketing: theory, models and application track at the Decision Sciences Conference held in Phoenix, Arizona. In 2003, I received the best research paper award at the American Association of Pharmaceutical Scientists on my paper on promotional response modeling. In 1997 I also received the best-applied paper award at the Society for Franchising Conference a pre-eminent conference in franchising organized by the International Franchising Association Educational Foundation. Three of the four awards were after my tenure at SJU.

Quality of Research Outlets

My publications have appeared in some of the best journals in multiple disciplines – pharmaceutical and healthcare marketing (International Journal of Pharmaceutical and Healthcare

Marketing (Cabell acceptance rate (20%), Impact factor (0.173)), Journal of Pharmaceutical Marketing and Management, Journal of Research in Pharmaceutical Economics, Journal of Medical Marketing (Cabell acceptance rate (21%), Impact factor (0.181)), Journal of Commercial Biotechnology (Cabell acceptance rate (30%), Impact factor (2.01), Pharmaceutical Executive, acceptance rate (20%), marketing (Journal of International Marketing (Cabell acceptance rate (8%) Impact factor (2.316)), Journal of Marketing Theory and Practice (Cabell acceptance rate (15%), Impact factor (0.545), in management (Journal of Business Venturing, Cabell acceptance rate (8%), Impact factor (3.954), Information and Management (Cabell acceptance rate (9%), Impact factor (2.217), operations (Journal of Operations Management, Cabell acceptance rate (7%), Impact factor (4.363)), and pharmacy (Journal of Social Administrative Pharmacy, Impact factor (2.35) Journal of Hospital Systems Pharmacy, Impact factor (2.1)). I would like to note that publishing in varied journals require skills and approaches that require understanding of the disciplines to recognize the work contributed to theory development and application to practice.

I have also presented in leading academic conferences such as American Marketing Association, Academy of Management Association, Decision Science Institute, Academy of Marketing Science World Marketing Congress, American Association of the Pharmaceutical Scientists, Northeast Business and Economics Association and Society of Competitive Intelligence Professionals (SCIP) Academic Conference.

Research Impact

The citations analysis on page 5 of this statement (Table R1) shows that most of my papers, including conference presentations, have been cited. The most frequently cited piece, so far, is my research published in Journal of Business Venturing (2000) paper that has been cited 125 times, followed by paper published in Information and Management 101 times, and in Journal of Operations by paper is cited 66 times. The total number of citations till June 2007 is over 350. Sixty five percent of the citations were in the last 5 years. Journal of Medical Marketing on their website listed my paper on Internet Marketing as one of the most read articles in their website (mmj.sagepub.com/reports/ most-read).

Several books published have cited my research papers. In chronological order they are:

1. Entrepreneurship, Theory, Process and Practice by Donald F. Kuratko, 10th Edition, Cengage Learning, 2016

2. Developments in Marketing Science: Proceedings of the Academy of Marketing Science, Celebrating America's Pastimes: Baseball, Hot Dogs, Apple Pie and Marketing? Kacy K. Kim Editor, 2015

3. Essentials of International Marketing by Donald L. Brady, M.E. Sharpe, 2014

4. Entrepreneurial Marketing: Global Perspectives, by Zubin Sethna, Rosalind Jones & Paul Harrigan, Emerald Publishing, 2013

5. Critical Issues for the Development of Sustainable E-Health Solutions, Edited by Nilmini Wickramasinghe, Rajeev K. Bali, Stefan Kim and Reima Suomi, Springer, 2012

6. Hotel Management and Operations edited by Michael J. O'Fallon and Denney G. Rutherford by Wiley & Sons, 2011

7. Pharmaceutical Markets and Insurance Worldwide by Avi Dor, Emerald, 2010

8. Reshaping the Boundaries of the Firm in an Era of Global Interdependence: Progress in International Business Research, by Jose Pla-Barber, Joaquin Alegra, Emerald, 2010.

9. Advances in Business and Management Forecasting, edited by Kenneth D. Lawrence and Ronald K. Klimberg, JAI Press, 2009

10. Marketing Management by Saxena, Tata-McGraw Hill, 2009

11. Energizing Management thorough Innovation and Entrepreneurship – Europe Research and Practice, edited by Mike Terziovski, Routledge, 2009

12. Advances in International Marketing: New Challenges to International Marketing, Volume: 20, edited by Rodolf R. Sinkovics and Pervez N. Ghauri, Emerald, 2009

13. The New Sociology of the Health Services, edited by Jonathan Gabe and Michael Calnan, Routledge, 2009

14. Handbook of Metrics for Research in Operations Management by Aleda Roth, Roger G. Schroeder, Xiaowen Huang and Murat Kristal, Sage Publishing, 2008.

15. E-Supply Chain Technologies and Management by Qingyu Zhang, Idea Group Inc., 2007

16. Anxieties and Management Responses in International Business, Rudolf Sinkovics and Mo Yamin, Palgrave Macmillan, 2007

17. Entrepreneurship: The Engine of Growth, edited by Maria Minniti, Praeger Publishing, 2007.

18. Economics and Management of Networks: Franchising, Strategic Alliances and Cooperatives, edited by Gerald Cliquet, George Hendriske, Mike Tuunanen and Josef Windsperger, Contribution to Management Science Series, Physica-Verlag – A Springer Company, 2007

19. Diffusion of Innovations in Health Service Organizations by Trisha Greenhalgh et. al., Blackwell Publishing, 2005.

20. Diffusion of Knowledge Management Systems: Mission Definitely Possible, edited by Shankar Shankaran and Alexander Kouzmin, Emerald, 2005

21. Economics and Management of Franchising, edited by Josef Windsperger, Gerald Cliquet, George Hendriske and Mika Tuunanen, Contribution to Management Science Series, Physica-Verlag – A Springer Company, 2004.

22. Research Methods in Pharmacy Practice, by Falicity Smith, Pharmaceutical Press, 2002.

23. Effective Small Business Management, Richard M. Hodgetts and Donald F. Kuratko, Wiley, 2000

A. My research papers that I have been aware of have been used in the PhD seminars and MBA programs at University of Maryland, University of Wisconsin, and University of Iowa. In LinkedIn, I have been recognized as a pharmaceutical and healthcare industry expert. Recently I was contacted by Prof. George Day, Geoffrey T. Boisi Professor of Marketing, and Co-Director of the Mack Institute for Innovation Management, at Wharton School of Business. He interviewed me to gain insights on the future of the pharmaceutical and healthcare commercial models. In his email to me after the interview Prof. Day comments,

"*We really benefited from your insights as we grapple with the complexities of the pharma commercial model. Looking forward to sharing our progress.*"

In addition, Prof. George Day, also invited me to join an invitation only conference with 10 experts to discuss the future models of pharmaceutical and healthcare in the fall of 2013 at the Mack Institute of Innovation at the Wharton School. I feel it is an honor and a testimony to my expertise and knowledge in this field of study.

Table R1: List of Publications

Pub.#	Publication
P23	Ghani, W., **Jambulingam, T.**, Sharma, R. (2018) *International Journal of Healthcare Management*
P22	**Jambulingam T.,** Joshi, M., Kathuria, R. (2018) *Management Dynamics*, 18 (1): 1-22
P21	Ghani, W., **Jambulingam, T**., Sharma, R. (2018) *Journal of Generic Medicines*, 14 92): 59-69.
P20	Smith, B., **Jambulingam, T.** (2018) *International Journal of Pharmaceutical and Healthcare Marketing*, 12 (2): 158-180
P19	**Jambulingam T,** (2017) *Journal of Commercial Biotechnology*, 24 (1): 48-55
P18	**Jambulingam, T** (2016) *Harvard Health Policy Review*, 15 (2): 14-18.
P17	**Jambulingam, T**, Carolin Schellhorn and Raj Sharma. (2016) *Journal of Commercial Biotechnology*, 22(1): 49-60.
P16.	**Jambulingam**, **T**, Franklin Carter & Ravi Chiturri (2015) *Journal of Marketing Management*, 3 (2): 1-10.
P15.	**Jambulingam, T.,** Kathuria, R., & Nevin, J. R. (2011).

	Journal of Marketing Theory & Practice, 19 (1), 39-56.
P14.	**Jambulingam, T.,** Ghani, W., & Sharma, R. (2010). *Journal of Commercial Biotechnology*, 16 (4), 313-330.
P13.	**Jambulingam, T.,** (2010) *Pharmaceutical Executive* (July): 39-42.
P12.	**Jambulingam, T.,** & Sharma, R. (2010). *Journal of Medical Marketing*, 10 (4), 332-343.
P11.	**Jambulingam, T**., Kathuria, R., & Nevin, J. R. (2009). *International Journal of Pharmaceutical and Healthcare Marketing*, 3(4), 305- 322.
P10.	**Jambulingam, T.,** Sharma, R. & Ghani, W. (2009) *International Journal of Pharmaceutical and Healthcare Marketing*, 3(3), 210- 235.
P9.	**Jambulingam, T**., Kathuria, **R.,** Doucette, W.R. (2005) *Journal of Operations Management*, pp. 23-42
P8.	**Jambulingam T.,** & Saxton T. (2002) *Journal of Pharmaceutical Marketing & Management*, 15(1): 73 - 95
P7.	Carter, F., **Jambulingam T.,** Gupta, V. & Melone, N. (2001) *Information & Management*, 38: 277-287.
P6.	Aurand, Timothy W., **Jambulingam, T.,** & Gorchels, L. (2000) *Academy of Marketing Studies Journal*, 4 (1): 1-16.
P5.	Doucette, William R., & **Jambulingam T.** (1999) *Journal of Social Administrative Pharmacy*, 16 (1); 26-37.
P4.	**Jambulingam T.,** Nevin. J. R. (1999) Journal of Business Venturing, 14: 363-395.
P3.	Gorchels, L., **Jambulingam T.,** & Aurand T.W. (1999) Journal of International Marketing
P2.	Mott, D., & **Jambulingam T.,** (1997) American Journal of Hospital Pharmacy, 54(5): 558-63.
P1.	**Jambulingam T.,** & Kreling D. H. (1995) Journal of Research in Pharmaceutical Economics, 6 (3): 39-60.

P = Publications

The findings of my research—past and ongoing—have significant managerial implications. Some of the areas where managers could use these findings include the factors that determine the entrepreneurial orientation of a firm, how diffusion of innovations of high-tech products occur, how to managing inter-organizational relationship and understand the influence of organizational structure in the supply chain context to enhance loyalty and how to hire right and develop curriculum to train business leaders to improve performance and to gain a competitive advantage.

According to the mission statement of the Saint Joseph's University, intellectual contributions (academic research) will be a mix of basic research, applied research and instructional development. My research portfolio has a mix of all three types. For example, my P1, P4, P15 and P20 is classified as basic research, P9 and P11 are classified as applied research, and P6, and P13 can be listed as instructional development research.

Further, the school aspires to prepare students for successful business careers around the world, which is directly in line with my teaching philosophy outlined in the section below. My research

focusing on the marketing and management of national and international pharmaceutical and healthcare firms, and with significant managerial implications will go a long way in supporting the school's mission.

Research Streams and Publications

Most of my papers fall under the big umbrella of Industrial Organizational Strategy, and are focused on four research themes as follows:

Organizational Structure and Conduct: The focus of papers **P8** and **P11** were on how inter-organizational structure influence performance. In **P8**, published in *Journal of Pharmaceutical Marketing and Management* (**JPMM**), we analyzed 66 international and intra-national transactions (alliances and acquisitions) in the pharmaceutical industry in a two years longitudinal study, to determine how transaction structure, inter-firm synergies (organizational and strategic fit) and motives (market, efficiency and organizational motives) influence performance using transaction costs, resource dependence and organizational learning theories. The study found that transaction structure and high levels of strategic fit between the firms had a positive impact on performance and the results yielded meaningful information on the success of transactions (alliances and acquisitions). Motives in relationship to synergies have a role in driving the transactional performance.

In **P15**, published in *Journal of Marketing Theory and Practice* (**JMTP**) using the resource advantage theory within the relationship marketing framework, we studied the mediating role of trust as a governance mechanism in the fairness–loyalty relationship under different types of interdependence structure between suppliers (wholesalers) and buyers (retailers) in the pharmaceutical supply chain. Our findings, based on data from retail pharmacies, demonstrate that only under conditions of symmetric interdependence, trust, as a governance mechanism, completely mediate the relationship between fairness and loyalty. Under conditions of both perceived independence (i.e., lack of interdependence) and asymmetric buyer dependence, however, trust does not mediate but fairness directly influences loyalty. Thus, fairness and trust influence loyalty, strengthening relationships in different ways under different conditions of interdependence. The findings have practical applications in managing supply chain relationships.

In another study **P11**, published in **IJPHCM**, we studied how trust as a governance mechanism mediate the relationship between fairness and loyalty in the pharmaceutical wholesaler-pharmacy relationship. Specifically, the paper seeks to understand if the two dimensions of fairness – procedural and distributive – contribute differently in fostering the two sub-dimensions of trust – credibility and benevolence. A counterintuitive insight was that procedural fairness was found to be more important than distributive fairness in influencing trust (credibility) and distributive fairness is more important than procedural fairness in influencing trust (benevolence). So, in order to manage customer loyalty, one has to understand the different types of fairness having different effects on different sub-dimensions of trust. In the hypercompetitive pharmaceutical wholesaling environment and the pharmaceutical manufacturing effort in disintermediation of the wholesalers, the findings are very useful for the wholesalers. The concept is applicable to the other dyads in the supply chain as well.

In **P1** published in the *Journal of Research in Pharmaceutical Economics* **(JRPE)**, the theoretical relationship between market structure (number of firms) and the conduct (pricing behavior) in the generic drug industry was investigated. Utilizing Porter's five forces model, the relevant competitive structure of the generic industry structure was identified. IMS Health data from four therapeutic categories and 15 products a multiple regression model was used to test the model. The results show that generic drug industry behaves as an oligopolistic competitive market tending toward a pure competitive model with price as the key determinant of competition. The analysis shows that generic companies enter all markets irrespective of the therapeutic category, popularity or duration of use of the drug product. The price erosion is directly proportional to the market entry aggressiveness in the first year. Thus, the Generic Price Competition and Patent Restoration Act of 1984 created a generic drug industry that never was significant before the legislation.

Organizational Conduct and Performance: Another area of interest for me is entrepreneurial orientation (EO) of an organization. Entrepreneurial orientation is an organizational conduct that has impact of the performance. Based on the seminal work done by Dess and Lumpkin (1996)[a], in P5 published in a *Journal of Social Administrative Pharmacy* (JSAP), we developed for the first time a multi-dimensional measure of entrepreneurial orientation for community pharmacies. The dimensions were innovativeness, proactiveness, autonomy, risk taking, competitive aggressive and work ethic. Work ethic was added based my earlier research in franchising. In addition, the antecedents to the pharmacy's EO and assess the relationship between levels of EO and provision of new services in pharmacy was tested. Data was collected via mail survey of pharmacies in nine states representing the regions in United States. Using a second-order confirmatory factor analysis, an 18-item measure of EO was found to have six dimensions as predicted. Four antecedents of an EO were identified: organicity of pharmacy structure, adequacy of resources, pharmacy type and environmental munificence. The proportion of high EO pharmacies providing five of seven innovative services was significantly higher than the proportion of low EO pharmacies providing the services. Those services are patient compliance monitoring, asthma care management, diabetes management, formal evaluation of patients' health risks and specialized compounding. We provided evidence of reliability and validity of a measure of EO, identified four antecedents of EO, and showed that EO is a useful indicator of whether a pharmacy will develop new pharmacy services. Pharmacy managers and researchers were encouraged to consider EO as a key facilitator in developing new services.

Following JSAP article, in P9, I published in *Journal of Operations Management* (JOM), we develop a service classification scheme based on the entrepreneurial orientation of organizations within the retail pharmacy industry. To date, service classification research has primarily taken a macro view, creating service typologies or taxonomies by using dimensions such as customer contact or degree of labor intensity. Such classification schemes, though helpful in deciphering critical marketing, management issues and positioning strategies between service industries, tend to treat an entire industry, such as airlines, as a single homogenous entity. However, organizations in the same industry often use intangible resources such as entrepreneurial orientation processes to compete with one another. Resource-Advantage Theory suggests that organizations utilize intangible resources to build long-term strategies and a sustainable competitive advantage leading to superior performance. We developed organization clusters based on entrepreneurial orientation as intangible resources to classify organizations within an industry. Using data from the retail

pharmacy industry, we tested if the orientations of the resultant groups within the pharmacy industry were related to their perception of the environment, organizational factors, and performance outcomes. Our JOM paper was published in 2005. In September 2011 issue of Entrepreneurship Theory and Practice (ET&P) the renowned scholars of entrepreneurship Professors Jeffrey G. Covin and G. T. Lumpkin, in their article "Entrepreneurial Orientation Theory and Research: Reflections on Needed Construct" commented the following as a high potential research focus.

> "*We believe that a configurational approach to EO research holds much promise, particularly when the multidimensional conceptualization of EO is adopted. For example, researchers when might employ cluster analysis to identify groups of firms with similar profile across the five dimensions of EO*."

In our research published in JOM we have attempted to shed some light on this topic of high interest in 2005. The measures developed for EO was cataloged in the "Handbook of Metrics for Research in Operations Management," published in 2008.

In our **P20** paper we are further expanding this research stream and link the EO with customer orientation (CO) using partial least squares (PLS), a component---based form of structural equation modeling (SEM) to identify the construct and measurement items that are more important in determining the outcomes, specifically to examine how entrepreneurial orientation and customer orientation influence healthcare (retail pharmacy) industry performance. Using a sample of the US retail pharmacies, the study applies partial least squares structural equation modeling to identify the direct and indirect effects of the entrepreneurial orientation constructs on company performance. The study also includes importance–performance analyses to prioritize for managers which orientations, dimensions and respective manifest items merit the most critical attention as contributors to pharmacy performance. We find that the entrepreneurial orientation has a significant impact on customer orientation and company effectiveness. We also find that three dimensions – innovation, risk-taking, and proactiveness – exhibit stronger importance and performance than autonomy and competitive aggressiveness.

Within an organization the adoption of a new technology (diffusion of innovation) evolves through three phases: initiation, adoption and implementation. In **P7**, published in Information and Management (**IM**), we attempted to study the adoption of a new information technology and factors that affect the adoption and implementation processes. We investigated such factors as advocacy, breadth of support, time of adoption, and intra-organizational communications. This paper examined the adoption process of five technology innovations from the telephone interview data of executives and analyzed using PROBIT and Hazard models. Organizations' adoption behavior was empirically examined as a multi-stage process. Participants responded to questions about the organization's adoption decisions, the adoption process, communication mechanisms used to facilitate adoption, and beliefs about the innovations. Several hypotheses are formulated and empirically tested. Several implications can be derived from the results. First an organization develops capabilities for using an innovation and the timing of that process if the participants consider that there are advantages in the innovation; beliefs are important to a successful adoption process.

Top management advocacy generally had little effect on adoption and that successful adoption of these innovations can often be characterized as a bottom-up, rather than top-down, process. However, innovations often do not require large initial capital outlays; they require highly professional `people resources. Primary advocacy is also important. However, depending on the stage and measure of adoption, results were not consistent and there is still a great deal to be learned about the effects of `intermediate level' advocacy on the adoption process.

The results of this research also have implementations for the use of communication mechanisms to support the adoption process for an innovation. Extensive use of communication mechanisms was found to affect timing more than probability of adoption. Training provided by the organization to its staff, a high resource, formal mechanism, generally had positive impact on speed of adoption. This is true whether the training is developed by in-house personnel or outside personnel. Also, the effect of communication mechanisms may vary based on the type of innovation being considered. Extensive use of formal communication mechanisms had a significant, positive, impact on adoption. Communication mechanisms requiring a high level of organizational commitment tend to have a significant, positive association with adoption. However, this effect is most evident when the mechanism is both high in resource commitment and formalism. We also found that mandates work. Bidding on contracts, which mandate the use of the innovation, is associated with both higher probability of movement through stages and earlier adoption. Note that these results do not imply anything about whether the innovation is used properly by the organization, once it is adopted. However, mandates do provide strong incentives for organizations to rapidly adopt and implement an innovation. Finally, there is support for the assertion that diffusion of innovations should be studied as a process consisting of multiple stages and measures. Results clearly show that the importance of adoption factors varies by stage and by adoption measure considered. Perceived advantage or disadvantages of the innovation are especially important early in the adoption process. Communication mechanisms have more impact later in the process. The adoption history, the smoothness and timing of the early stages, also significantly affects later stages.

Overall, the results of the research provide some general insights into the adoption process of information technology innovations. This study has implications to pharma as companies are constantly adopt new technologies for competitive advantage, whether in-license new technologies, processes and software platforms.

Finally, the **P22** paper that was published in **Management Dynamics.** In the era of increasing need for customer-centric marketing, the growth of technology such as the
Web-based customer relationship management (CRM) has enabled pharmaceutical firms to develop new capabilities to sustain competitive advantage with superior marketing strategies, which include formulating unique, direct relationships with customers. To compete by integrating the online technologies across all aspects of a firm's operations, translates into the need for developing new skills as traditional ways of competing become insufficient. Towards this end, pharmaceutical firms have seized the opportunity to institute relationships with customers (physicians and patients) with the use of the Web. Our research focused on developing a technique that would allow for benchmarking Web-based CRM strategies of firms in any industry. We used the US pharmaceutical industry as a setting to demonstrate how our technique can be used to avoid the typical blind spots of competitor analysis. We used a method called Analytic Hierarchy Process

(AHP) to analyze seven firms, selected by executives from the pharmaceutical industry, to compare their Web-based CRM strategies. Results suggest that three of the seven firms were far ahead in the adoption of the Web-related to the CRM. One had more focused efforts in patient relationship (patient-centric) where as another had a very high focus on physician relationship. The framework, criteria and methodology are useful for industry to use as competitive intelligence and analysis tool.

In our study **P17** we used an interesting methodological contribution by exploring Rasch modeling approach to ranking the top 15 firms in the pharmaceutical industry by their overall financial performance. Using an initial set of ratios spanning multiple dimensions of firm financial performance, we select the ratios that are compatible with the requirements of the Rasch model for this industry during 2002- 2013. We then identify the firms that most frequently ranked among the top five performers. Three firms stand out as consistently disclosing the required data and showing up at the top of the performance spectrum. Our approach offers a new perspective on the valuation of managers and their firms.

Impact of (Sales and Marketing) Regulations on Firm Behavior: Pharmaceutical industry is highly regulated. Changes in the regulations or guidelines to the industry have significant impact on the conduct and performance of the industry. Four papers – P10, P14, P12 & P21 deal with impact of regulations of pharmaceutical sales and marketing on the economics of the firms or industry.

The purpose of the paper **P10**, published in the **IJPHCM**, is to investigate the wealth effects of the issuance of guidelines by the Office of Inspector General (OIG) to encourage pharmaceutical manufacturers to use internal controls or self-regulation "to efficiently monitor adherence to applicable statutes, regulations, and program requirements" in their marketing to the physicians. Using the standard event-study methodology the impact on stock price of 12 large pharmaceutical firms around four events leading up to the final guidance issued by the OIG was examined. Eventus ® software and CRSP data from Wharton Research Data Services was used to conduct analysis. The overall results indicate a net wealth loss and it varied by company and the portfolio of products. The issuance of high-level government policy initiative triggers a pharmaceutical industry response that in turn mitigated firms' questionable marketing practices. The government accomplishes this without instituting regulation but by taking the dialogue to a wide-ranging and highly public forum. The empirical results suggest that a public policy initiative that impacts shareholder wealth could alter firm (industry) behavior thereby sparing government from enacting regulation and potentially saving exorbitant regulatory enactment, enforcement, and policing costs. The results also provide credence to the argument that the hybrid systems, ones that combine industry rule making with government oversight, provide the greatest potential for overall benefits to society.

The biotech industry is quite different from the traditional pharmaceutical companies. The biotech firms did not have the challenges of patent expiry compared to the small molecule driven pharma, which is facing intense competition. With lack of clear legislation for generic version of biotech products (biosimilars) the competitive landscape is different. With that said, **P14**, the published study in *Journal of Commercial Biotechnology* (**JCB**), investigated the response of the top 10 biotech firms to the OIG guidelines using the standard event study methodology. Is there a

contagion effect on the biotech industry? Eventus ® software and CRSP data from Wharton Research Data Services was used to conduct analysis. We found that the biotech with less threat from generics also responded to the guidelines similar to the large pharma with a significant welfare loss. It seems that as part of the self-regulating guidelines issued by the PhRMA the trade organization for the pharmaceutical industry, the biotech organization also adopted similar guidelines to become compliant with marketing practices as well.

In **P21**, our study that was published in *Journal of Generic Medicines* examined the contagion effect on shareholders' wealth of large generic firms to the issuance of guidelines by the Office of Inspector General "to efficiently monitor adherence to applicable statutes, regulations and program requirements" of the branded pharmaceutical companies. These guidelines prod pharmaceutical manufacturers to employ internal controls and self-regulation while marketing to the physicians. We use a standard event-study methodology to measure the effect on the value of nine large generic firms around four events including the final guidance issued by Office of Inspector General. The results show that there is a contagion effect with an overall loss in net wealth of large generic firms' shareholders. The US government's policy guidance necessitated pharmaceutical industry to reexamine and refine for the better, its marketing practices. The government achieved this change in pharmaceutical industry's behavior without actually introducing any regulation suggesting the efficacy of self-regulation. Our findings suggest that there is a contagion effect of Office of Inspector General guidelines on generic drug industry due to facilitated self-regulation by branded pharmaceutical industry. Thus, the direct implication is that any regulatory event that is meant for one firm or a group of firms in the health sector could adversely impact peer firms in the same industry (pharmaceutical) or related industries such as biotechnology or generic industries. In other words, the study shows that government's public policy initiatives that effect the value of the targeted firms could change not only the firms'/industry's behavior but also let government achieve its objectives without contemplating additional regulations. This in turn, may accrue significant cost savings for the government in avoiding the regulation and its related measures. Our results also support an argument that a mechanism that combines industry self-regulation with government monitoring, lends the greatest opportunity for the overall welfare of the society. The key contribution of this study is that OIG regulation had spill-over effects on the generic drug industry.

The study **P12** that is published in *Journal of Medial Marketing* **(JMM)** was an interesting one. The Food and Drug Administration on April 2nd 2009 issued 14 major pharmaceutical companies a warning letter for the internet advertising, effectively curtailing an aspect of internet marketing by pharmaceutical industry. Given that the efficient market hypotheses suggest that stock prices fully reflect all publicly available information and are unbiased indicators of firm value, this article presented an analysis of stock market reactions of pharmaceutical firms around the time of the FDA announcement, using both regular and abnormal returns. We analyze two groups of firms, those that received the warning letters and those that did not receive the letters. We find a significantly negative stock market reaction for both groups of firms, suggesting that the letters had negative impact on shareholder's value to the industry as a whole. Using this natural experiment, we were able to quantify the impact of internet marketing on the performance of the pharmaceutical industry. The results indicate that internet marketing is important, and had a financial impact of $27.3 billion-dollar impact on the firms that received the letter and $18.4 billion on the firms that did not receive the letters. Again, we found that the warning letters had negative

impact on firms that received the letter, and a contagion effect on the firms that did not receive the letter as well. We proposed that the industry should work in tandem with the FDA to develop better guidelines on the appropriate use of the internet for the marketing of pharmaceuticals. The cost for pharmaceutical firms for not utilizing the internet capabilities to communicate value to the stakeholders can be significant.

As a follow up to P12, our research paper **P23** was recently accepted by *International Journal of Healthcare Management* for publication. Our work was motivated by prior evidence of significant negative wealth effects reported by Jambulingam & Sharma (2010), based on the Food and Drug Administration (FDA) April 2, 2009, warning letters to 14 major pharmaceutical companies pertaining to search engine advertising, in an effort to stop one critical dimension of internet marketing by pharmaceutical industry. As a consequence, we expect the overall market for branded drugs to shrink. This shrinkage in future will affect market for generics, in turn negatively impacting future cash flows of generic firms – a contagion effect. This empirical study tests contagion effect by measuring changes in shareholders' wealth of a select sample of large generic firms around regulatory event. Using standard event-study methodology, we investigate whether this contagion wealth effect due to internet advertising restrictions on pharmaceutical firms do carry over to generic firms since they do not advertise themselves. Our results show a significant and negative wealth effect (contagion) for shareholders of generic firms on event day 0. We also report this shareholder wealth loss, in dollar terms, to be of 783 million, on Event day 0 (when FDA posts the letter). Internet-based online marketing, an interactive promotional media, is increasingly becoming a key communication channel as part of the multichannel marketing strategy for the pharmaceutical companies for improved physician and patient engagement. This study clearly validates that the impact of internet marketing has significant impact on both branded and generic industry. This study illustrates that the methodology used in the study is an approach the impact of internet or social media impact on the pharmaceutical and generic pharmaceutical industry. Our findings have implications for policy makers and regulators as additional policies and regulations are contemplated.

After several drugs such as Fen-phen and Vioxx were linked to the withholding of safety data and deaths and disabilities linked to the marketing of those drugs, the public trust on the drug industry and also on FDA bottomed out. In 2007, Congress took action instituting a new program at FDA called Risk Evaluation and Mitigation Strategies (REMS) as a drug safety measure and to ensure that the benefits of a drug or biological product outweigh its risks. The REMS program was instituted in March of 2008. After more than 125 drug products had different levels of REMS program in place there was no clarity on how these REMS program can be used for successful communication with the physicians and patients. My study **P13**, published in *Pharmaceutical Executive* (**PE**), a premier journal targeted toward the executives in the industry and editorially reviewed article, attempted to clarity the concept of REMS, its role in drug safety, how pharmaceutical firms can utilize the REMS programs to build trust in their products and how to utilize the collected REMS data to optimize marketing resource allocation decisions. The executives in the industry very well received the study. I was invited by two major pharmaceutical companies to share my thoughts on how the REMS program can benefit pharma in their ability to communicate with the physicians and patients.

Promotion and pricing are two critical elements of marketing of pharmaceuticals. Studies **P16**, **P17** & **P19** explores the importance of these strategies for pharmaceuticals. In study **P16**, that was published in *Journal of Marketing Management* we explored under what conditions consumers perceive DTC (Direct-to-Consumer) advertising is valuable? The IMS Health (now IQVIA) survey data that are nationally representative probability panel data was used in the study to test the hypothesis. sample. Panelists were retained for at least one year and may continue to report for two or more years. Close to 3000 completed surveys were analyzed. IMS defines the study objectives as follows. (1) To analyze consumer awareness and reactions to recent consumer-oriented campaigns (DTC advertisements in general, direct-to-patient programs, and patient brochures). (2) To examine the likelihood of consumers' taking specific actions as a result of exposure to pharmaceutical company sponsored programs. The sample we have corresponds to the most recent survey and has 771 respondents. We retain a randomly selected 1/3 of the observations as a holdout sample. The data was analyzed using multiple regression. The results from this research show: 1) consumers with children who also seek advice from pharmacists perceive DTC advertising to be valuable; 2) educated consumers who have visited a doctor recently (in last 6 months) perceive DTC advertisements to be less valuable; and 3) disease condition of the consumer significantly impacts perceived value of DTC advertising.

In the study **P17**, published in *Harvard Health Policy Review*, the complexity of pricing in the United States pharmaceutical supply chain was explored. First, a brief description of the supply chain for pharmaceuticals was described followed by a discussion on drug pricing, reimbursement and mark up of different channel members in the supply chain. In the changing regulatory and political environment for pricing, key policies issues were discussed on how they would affect the future of drug pricing in US.

One way to reduce to cost of pharmaceuticals is to improve efficiency in the R&D drug development process. It costs an estimated $2.1 billion dollars to develop a drug according to a study from the Tuft's University, a barometer industry uses for the cost of drug development. In this study I explored the importance of marketing in shaping R&D decisions thus improving efficiency in drug development. In this study **P19**, a framework was developed to highlight the importance of building a marketing led cross-functional team that integrates the R&D, and commercialization process in an early stage Biopharma and MedTech company. Marketing should play a prominent role in the cross-functional team at the earliest stages of company formation and product development to identify unmet need, design the development plan, shape the product life cycle, position the product in the competitive set, and understand all market drivers and competitive factors that are essential to ensure commercial success. In particular, in this paper, the focus was on the importance of creating an appealing target product profile (TPP) and describe the rational and methodology for creating the TPP. Drug development is a high risk, high cost, high reward undertaking, and the TPP provides a market-guided approach to development of drugs more quickly, inexpensively, and with a higher rate of success.

Selection and Training of Business Leaders: The final stream of research was to develop criteria in selecting ideal candidate to run entrepreneurial organizations. In our first study **P3**, published in *Journal of International Marketing* (**JIM**) we identified skills for international marketing managers that are necessary to run successful businesses internationally. The perceptions of executives from three countries: Japan, Germany and United States were compared. We found that

the US executives wanted their international marketing managers to "think globally" where as the Japan and German counterparts wanted their international marketing managers to "act locally". We found that the Japanese and German business were global far longer than the US business and had ingrained in the global culture and have been incorporating cultures to act locally. Given these insights we were able to propose diverse hiring and training needs of marketing managers in these countries. As a follow, up we published **P6** in *Academy of Marketing Studies Journal* (**AMSJ**) were competencies of international marketing managers were identified and how those competencies can be integrated into an international marketing curriculum. Subsequently, the paper illustrates how a marketing curriculum can be developed, or modified, utilizing a tri-country model in conjunction with an established cross-cultural training model developed for training within a multinational corporate setting. Even though the executives participated in the study were from multiple industries, significant proportion of them (greater than 55%) were from pharmaceutical and healthcare industries. Since the competencies did not differ by industry we used all the data in this study to generalize to the marketing academics and practitioners.

Agency theory suggests that an efficient contract between a franchisor (principal) and a franchisee (agent) could be established by the use of selection criteria that would screen prospective franchisees based on their likely future outcomes desired by their franchisors. Franchisors can use franchisee selection criteria as a key input control to enhance the outcomes of their future franchisees. This article, **P4**, published in *Journal of Business Venturing* (**JBV**) examined the relationship between key franchisee selection criteria such as franchisees' financial capability, experience and management skills, demographic characteristics, attitude toward business dimensions (perceived innovativeness, desire for personal development, seek work-related challenges, personal commitment to the business, and business risk-taking), and key measures of outcomes desired by franchisors (perceived cooperation, satisfaction with the business decision, and franchisee opportunism). The findings show that certain franchisee attitudes toward business can be used as an effective input control strategy by franchisors because they explain a substantial portion of the variance in franchisees' outcome desired by franchisors. About 20% of the sample was franchisees in the healthcare industries. We did not find major differences in the responses between franchisees in the healthcare vs. non-healthcare and hence used together to publish the results.

The final article in this theme, **P2**, was published in the *American Journal of Health-Systems Pharmacy* (**AJHSP**), on factors impacting Wisconsin Pharmacists'' in the hours supplied to the labor market. The labor economic theory suggests that characteristics of workers, economic factors, and characteristics of employer influence the amount of labor supplied to a market. When the study was conducted there was acute shortage of pharmacists in the state and there was a need to understand what factors determine labor supply for this healthcare professional. Using seven years of cross-sectional survey data from the pharmacists in the state we conducted a path analysis to identify the variables that influence pharmacists' decision about the number of hours worked per week. We found that the pharmacist's gender, job position and age had he greatest impact on the hours worked per week by the pharmacist. The implications were used to develop policies to alleviate the shortage. A similar study could be utilized to understand shortage issues among other healthcare professionals.

*Future Research***:**

Expanding the **P17** publication on pricing I am now working on creating a policy framework for making drugs affordable in US. The findings will be presented in the Life Sciences of the Future conference on Oct. 29th and potentially could be presented at the Marketing and Public Policy Conference in May of 2019 (I am submitting my paper for review for the conference by the end of this month). I also published an article in the Decision Science Institute 2014 Annual Conference proceedings titled "Patterns of Supply Chain Integration in a Service Setting: Antecedents and Relationship Effectiveness." The paper is now being developed for submission to the Journal of Supply Chain Management, a premier journal in Supply Chain Management. This article is an extension of the research that I published in **P11** and **P15.**

Presentation of Refereed Papers

International

Jambulingam, T. & Kathuria, R. (2017-2018, September). *Impact of Medication Non-adherence on Pharmaceutical Supply Chain.* Decision Science Institute Annual Conference, Washington DC, District of Columbia.

Jambulingam, T., Schellhorn, C., & Sharma, R. (2014-2015, May). *A Rasch Perspective on Firm Financial Performance in the Pharmaceutical Industry.* Academy of Marketing Science, Denver, Colorado.

Jambulingam, T., Schelhorn, C., & Sharma, R. (2014-2015, March). *A Rasch Perspective on Firm Financial Performance in the Pharmaceutical Industry.* Global Academy of Business and Economic Research, Orlando, Florida.

Jambulingam, T. & Kathuria, R. (2014-2015, November). *Patterns of Supply Chain Integration in a Service Setting: Antecedents and Relationship Effectiveness.* Decision Science Institute Annual Conference, Tampa, Florida.

Velan, P. & Jambulingam, T. (2013-2014). *Medicine Disposal: Consumer Awareness and Environmental Concerns.* American Association of Pharmaceutical Scientists (AAPS), San Antonio, Texas.

Jambulingam, T. (2011-2012). *Estimating the Spill Over Effects of Pharmaceutical Internet Marketing on the U.S. Generic Drug Industry.* International Conference on Service Management, New Delhi, India.

Sharma, R. & Jambulingam, T. (2011-2012). *Does Internet Marketing Matter to the Generic Drug Industry?* International Conference on Service Management, New Delhi, India.

Jambulingam, T. & Sharma, R. (2010-2011). *Estimating the Spillover Effects of Pharmaceutical Internet Marketing on the Generic Drug Industry.* International Academy of Business and Public Administration Disciplines, Orlando, Florida.

Jambulingam, T., Kathuria, R., & Nevin, J. (2010-2011, November). *The Mediating Role of Trust under Varying Conditions of Supplier-Buyer Interdependence.* Decision Science Institute, San Diego, California.

Sharma, R. & Jambulingam, T. (2010-2011, January). *Does Internet Marketing Matter to Generic Drug Industry?* International Academy of Business and Public Administration Disciplines, Orlando, Florida.

Jambulingam, T., Kathuria, R., & Nevin, J. R. (2009-2010). *Impact of Interdependence on Fairness-Trust-Loyalty Relationship.* Academy of Marketing Science World Marketing Congress, Oslo, Norway.

Jambulingam, T., Sharma, R., & Ghani, W. (2008-2009). *Welfare Effects of the OIG Guidelines on the Large Pharmaceutical Companies.* American Marketing Association Public Policy and Marketing Conference, Philadelphia, Pennsylvania.

Jambulingam, T., Nevin, J. R., & Kathuria, R. (2007-2008, November). Antecedents to Supply Chain Integration: A Transaction Cost Theory Perspective. Decision Science Institute, Phoenix, Arizona.

Joshi, M. P., Jambulingam, T., & Kathuria, R. (2006-2007, November). *Competitive Intelligence Using AMC Perspective.* Decision Science Institute, San Antonio, Texas.

Jambulingam, T., Kathuria, R., & Nevin, J. R. (2005-2006, August). *Impact of fairness and trust on loyalty under varying conditions of supplier-buyer interdependence.* Academy of Management Conference, Honolulu, Hawaii.

Jambulingam, T., Kathuria, R., & Nevin, J. R. (2004-2005, November). *Effect of Supplier Fairness on Buyer Loyalty: Does Trust Mediate the Relationship?* Decision Science Institute, Boston, Massachusetts.

Kathuria, R. & Jambulingam, T. (2002-2003, November). *Service Competence of Pharmacy Types: A Comparative Analysis by Resources and Performance.* Decision Science Institute, San Diego, California.

Jambulingam, T., Kathuria, R., & Doucette, W. (2002-2003, August). *Developing Classification Schemes within a Service Industry: The Case of Retail Pharmacy Industry.* Academy of Management Conference, Denver, Colorado.

Joshi, M., Jambulingam, T., DeCarlos, D., & Kathuria, R. (2001-2002, November). *Measuring e-Business Activities of Pharmaceutical Firms in Customer Relationship Management.* Decision Science Institute, San Francisco, California.

Jambulingam, T. & Nevin, J. (2000-2001). *Exploring the Effect of Supplier Fairness on Reseller Loyalty.* American Marketing Association, Scottsdale, Arizona.

Jambulingam, T. & Levin, D. (2000-2001). *Establishing a Competitive Intelligence Department within a Pharmaceutical Firm.* Society of Competitive Intelligence Professionals Academic Conference, Philadelphia, Pennsylvania.

National

Jambulingam, T. (2013-2014). *Big Data – Can it Create Value and Competitive Advantage for Pharma?* Pharmaceutical Management Science Association, Orlando, Florida.

Jambulingam, T. (2009-2010). *Measuring the Impact of Strategic Decisions in a Simulation Based Strategy Course.* Academy of Business Education / financial Education Association, Ft. Lauderdale, Florida.

Latta, M. & Jambulingam, T. (2005-2006, March). *Drivers of and potential barriers to pharmaceutical sales.* Association of Marketing Theory and Practice, Hilton Head, South Carolina.

Joshi, M., Jambulingam, T., & Kathuria, R. (2003-2004, November). *Measuring E-Business Activities of Pharmaceutical Firms in Customer Relationship Management.* Southern Management Association, Clearwater, Florida.

Regional

Jambulingam, T. (2012-2013). *Differential Impact of Entrepreneurial Orientation on Performance Outcomes.* 8th Annual Mason Entrepreneurship Research Conference-George Mason University, Fairfax, Virginia.

Jambulingam, T. (2011-2012). *Estimating the Spatial Distribution of Adult Obesity in Indiana-Implications for Marketing and Public Policy.* Northeast Business and Economics Association, Philadelphia, Pennsylvania.

Joshi, M., Jambulingam, T., & Kathuria, R. (2010-2011, September). *Benchmarking Web Based CRM Strategies of Pharmaceutical Companies: A Competitive Analysis Using Analytic Hierarchy Process.* Northeast Business and Economics Association, Morristown, New Jersey.

Presentation of Non-Refereed Papers

International

Jambulingam, T. (2013 – Present). R&D Marketing Interface in the Biopharmaceutical and MedTech Industries, Biotechnology Industry Organization (BIO) Annual Conferences. Presented in the conference every year since 2013 as an invited speaker.

Jambulingam, T. (2011-2012). *Role of Trust in Organizations: Impact on Customer Loyalty and Retention.* Loyola Institute of Business Administration, Chennai, India.

Jambulingam, T. (2011-2012). *Role of Trust in Organizations: Does it Matter in International Business Scenarios.* Anna University - School of Management Studies, Chennai, India.

Jambulingam, T. (2011-2012). *Career Options in Biotechnology: Do you know your choices?* Bharathidasan University - Life Sciences and Business, Trichi, Tamil Nadu, India.

Jambulingam, T. (2007-2008, March). *Exploring New and Existing Tools for Information Gathering and Analysis.* Competitive Intelligence in Pharma USA, Philadelphia, Pennsylvania.

Jambulingam, T. (2005-2006, April). *Where do you stand? Exposing the Impact of Medicare Part D.* The 2nd Annual Longitudinal Patient Data Conference held by Institute for International Research, Philadelphia, Pennsylvania.

Jambulingam, T. (2003-2004, April). *Pricing in the Pharmaceutical Distribution System.* Pricing Rx Pharmaceuticals hosted by Henry Stewart Conference Studies, Washington D.C., District of Columbia.

Local

Jambulingam, T. (2010-2011). *How fairness garners loyalty in the pharmaceutical supply chain: Role of trust in the wholesaler-pharmacy relationship.* Haub School of Business Research Forum, Philadelphia, Pennsylvania.

National

Jambulingam, T. (2013-2014). *Impact of Big Data on Business Model of Pharma.* Big Data & Analytics for Pharma Conference, Philadelphia, Pennsylvania.

Jambulingam, T. (2013-2014). *Big Data.* Big Data & Analytics for Pharma Conference, Philadelphia, Pennsylvania.

Jambulingam, T. (2007-2008). *Current and Future Trends in the Pharmaceutical Manufacturing Industry.* Pharmaceutical Printed Literature Association 2008 Annual Meeting, Philadelphia, Pennsylvania.

Jambulingam, T. (2007-2008, October). *Innovations in Consumer and Physician Research.* Marketing Research Effectiveness, Philadelphia, Pennsylvania.

Jambulingam, T. (2007-2008, September). *Convergence Marketing Strategies and the Changing Customer: Defining the Future Role of the Sales Rep to Ensure.* PharmaForce, Philadelphia, Pennsylvania.

Jambulingam, T. (2005-2006, May). *Future Trends in Pharmaceutical Packaging.* 14th Annual National Symposium on Patient Compliance held by Healthcare Compliance Packaging Council, Philadelphia, Pennsylvania.

Regional

Jambulingam, T. (2009-2010). Does REMS (Risk Evaluation and Mitigation Strategies) enhance or hinder commercial brand value? REMS and Patient Compliance Conference, Princeton, New Jersey.

Jambulingam, T. (2007-2008, May). *Overview of the U.S. Health Care Delivery.* Prescriptions for Healthcare Reform, Philadelphia, Pennsylvania.

Non-Refereed Articles

Jambulingam, T. (2006). Estimating the Spatial Distribution of Adult Obesity in Indiana: Implications for Marketing and Public Policy. *Obesity*.

Invited Articles/Reviews

Jambulingam, T. (2006). Training Top Talent. *Future Pharmaceuticals*.

Jambulingam, T. (2001). Websites as Tools for Relationship Marketing. *Product Management Today*.

Monograph

Doucette, W. R. & Jambulingam, T. (1998). *Drug Wholesaler and Customers: Attitudes and Expectations on Current and Future Service Integration*. Washington DC: National Wholesale Druggists' Association (now Healthcare Distribution Management Association (HDMA)).

Cases

Jambulingam, T. (2006). Developing a Marketing Strategy for Acomplia -an Anti-Obesity Drug. *Use in Pharmaceutical Marketing Executive MBA Program and Industry Executive Training*.

Research Grants

Funded

2015-2016: Jambulingam, T. Summer Grant, Saint Joseph's University
2011-2012: Jambulingam, T. Pfizer Fellowship, Principal Investigator, Pfizer Inc. $35,000
2005-2006: Jambulingam, T. Obesity Research, Principal Investigator, GOV-Centers for Disease Control and Prevention (CDC). $10,000
2003-2004: Jambulingam, T. Obtained a Grant from American Association of Retired People (AARP) with co-investigator, Dr. Albert Wertheimer - $10,000, Temple University.
2003-2004: Jambulingam, T. Summer Grant, Saint Joseph's University.

1999-2000: Jambulingam, T. Summer Grant, Saint Joseph's University.

Faculty Development

Professional Seminars / Workshops

2010: Art and Craft of Case Discussion Leadership Program at Harvard Business School Publishing. This event is organized and presented by the Harvard Business School Faculty (CPE: 20) Boston, Massachusetts.

2008: Integrating Ethics in the Curriculum Training. Conducted by the Arrupe Center of Business Ethics (CPE: 40) Philadelphia, Pennsylvania.

Awards-Honors

Award

2017: Recipient - Extraordinary Achievement in Teaching Award Saint Joseph's University
2012: Arrupe Center Research Fellowship Arrupe Research Center for Business Ethics.
2012: Pfizer Fellowship Pfizer.
2010: Highly Commended Paper for the articles published in International Journal of Pharmaceutical and Healthcare Marketing for the Year 2009 Emerald Literati Network 2010 Awards for Excellence.
2007: Best Paper Award, Antecedents to Supply Chain Integration: A Transaction Cost Theory Perspective Decision Science Institute.
2005: Recipient of 2005 Extraordinary Achievement in Teaching Award Saint Joseph's University.
2003: Best Paper Award, Promotional Response Modeling for Pharmaceuticals American Association of Pharmaceutical Scientists.
2003: Recipient - Extraordinary Achievement in Research Award Saint Joseph's University.
1997: Received Annual Distribution Research and Educational Foundation Dissertation Proposal Award sponsored by National Wholesalers Association along with the Channels of Distribution Special Interest Group. Received cash award of $2,500. American Marketing Association.
1997: Received Best Paper Award at the Society of Franchising Conference International Franchise Association Educational Foundation.
1979-1985 - National Merit Scholarship Government of India.

Honors

2005: Inducted into Beta Gamma Sigma American Honor Society of Business.
2003: Elected as Chair-Elect of Economic, Marketing and Management Sciences (EMMS) American Association of Pharmaceutical Scientists (AAPS).
2003: Served as external reader in the dissertation (PhD) committee in Marketing at Columbia University.

2002: Elected as Vice-Chair of Economic, Marketing and Management Sciences (EMMS) American Association of Pharmaceutical Scientists (AAPS).
2001: Elected as Sectary of Economic, Marketing and Management Sciences (EMMS) American Association of Pharmaceutical Scientists (AAPS).
1996: Inducted into Rho Chi American Honor Society of Pharmacy.

Courses Taught by Programs

I. Undergraduate Pharmaceutical and Healthcare Marketing – 7 courses
1. PMK 150 - Freshman Seminar - Undergraduate
2. PMK 211 - Pharmaceutical Marketing Environment - Undergraduate
3. PMK 221 - Pharmaceutical Marketing Research - Undergraduate
4. PMK 341- Channels and Pricing
5. PMK 461 - Pharmaceutical Marketing Strategy I (writing intensive)
6. PMK 471 - Pharmaceutical Marketing Strategy II
7. PMK 465 - Advanced Marketing Research

II. Executive MBA ACE Program for Pharmaceutical and Healthcare Marketing – 9 courses
1. MPE 620 - Supply Chain Management
2. MPE 625 – Creating Effective R&D
3. MPE 640 - Pharmacoeconomics
4. MPE 650 - Competitive Analysis
5. MPE 670 - Pricing
6. MPE 715 - New Product Launches
7. MPE 780 - Future Issues
8. MPE 795 – Capstone
9. MPE 781 – Health Policy

III. Executive MBA Online Program for Pharmaceutical and Healthcare Marketing – 9 courses taught over the past 15 years
1. MPE 620 - Supply Chain Management
2. MPE 625 – Creating Effective R&D
3. MPE 640 - Pharmacoeconomics
4. MPE 650 - Competitive Analysis
5. MPE 670 - Pricing
6. MPE 715 - New Product Launches
7. MPE 780 - Future Issues
8. MPE 795 – Capstone
9. MPE 781 – Health Policy

IV. Executive MBA Lancaster General Hospital (LGH) Program – 4 courses
(Customized program using the data and strategic plan from LGH)
1. Healthcare Innovations (New Preparation 2013)

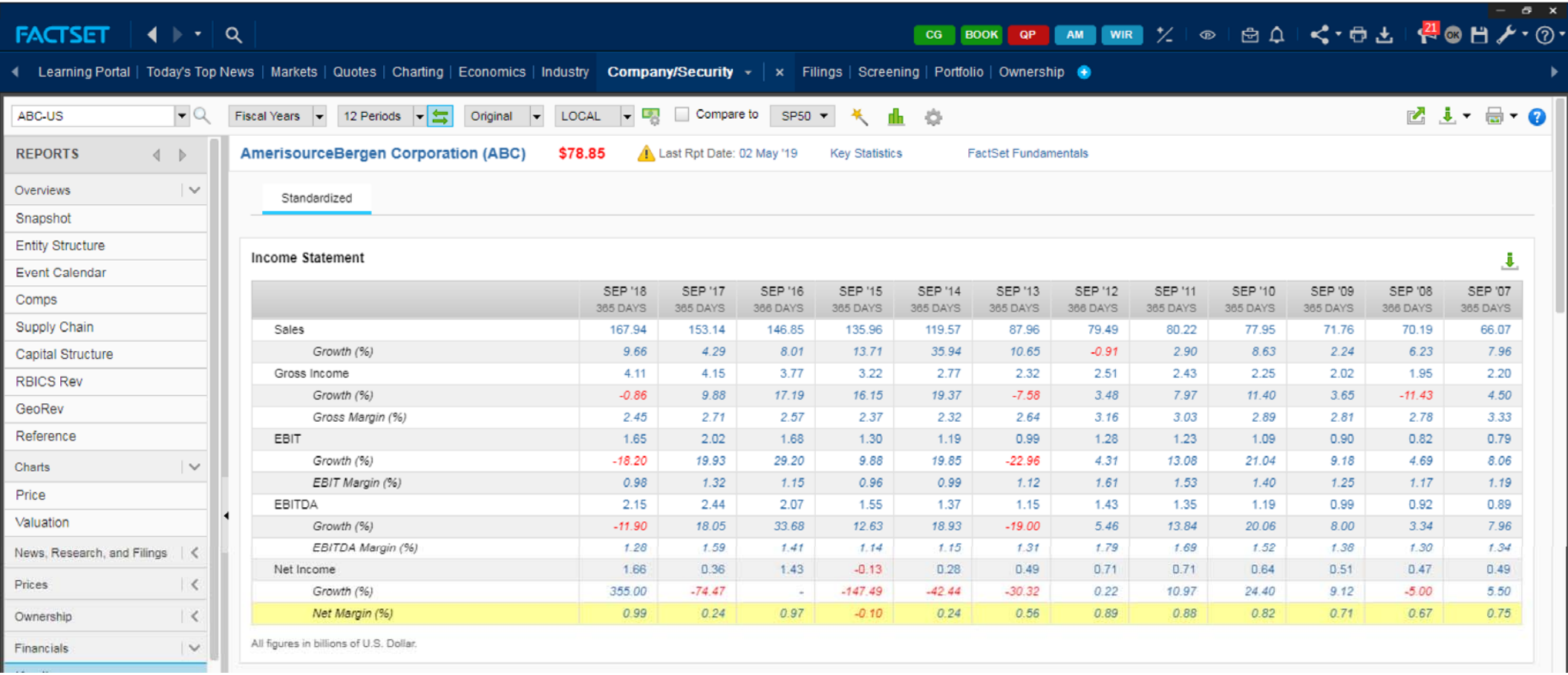
2. Supply Chain Management (New Preparation 2014)
3. Health Care Strategy (New Preparation 2014)
4. Capstone (New Preparation 2015)

IV. Executive MBA PCOM program – 2 courses
1. Healthcare Innovations (New Preparation 2017)
2. Supply Chain Management (New Preparation 2017)

IV. Executive Master's Food Marketing Program – 1 course
1. FMK 762 Nutrition: Issues for Food Marketers

IV. General MBA program – 3 courses
1. MKT 501 Marketing Concepts
2. PMK 650 Pricing in Healthcare
3. PMK 620 Supply Chain Management

Appendix C



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- Event Calendar
- Comps
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- Capital Structure
- RBICS Rev
- GeoRev
- Reference
- Charts
- Price
- Valuation
- News, Research, and Filings
- Prices
- Ownership
- Financials

AmerisourceBergen Corporation (ABC) $78.85 Last Rpt Date: 02 May '19 Key Statistics FactSet Fundamentals

Standardized

Income Statement

	SEP '18 365 DAYS	SEP '17 365 DAYS	SEP '16 366 DAYS	SEP '15 365 DAYS	SEP '14 365 DAYS	SEP '13 365 DAYS	SEP '12 366 DAYS	SEP '11 365 DAYS	SEP '10 365 DAYS	SEP '09 365 DAYS	SEP '08 366 DAYS	SEP '07 365 DAYS
Sales	167.94	153.14	146.85	135.96	119.57	87.96	79.49	80.22	77.95	71.76	70.19	66.07
Growth (%)	*9.66*	*4.29*	*8.01*	*13.71*	*35.94*	*10.65*	*-0.91*	*2.90*	*8.63*	*2.24*	*6.23*	*7.96*
Gross Income	4.11	4.15	3.77	3.22	2.77	2.32	2.51	2.43	2.25	2.02	1.95	2.20
Growth (%)	*-0.86*	*9.88*	*17.19*	*16.15*	*19.37*	*-7.58*	*3.48*	*7.97*	*11.40*	*3.65*	*-11.43*	*4.50*
Gross Margin (%)	*2.45*	*2.71*	*2.57*	*2.37*	*2.32*	*2.64*	*3.16*	*3.03*	*2.89*	*2.81*	*2.78*	*3.33*
EBIT	1.65	2.02	1.68	1.30	1.19	0.99	1.28	1.23	1.09	0.90	0.82	0.79
Growth (%)	*-18.20*	*19.93*	*29.20*	*9.88*	*19.85*	*-22.96*	*4.31*	*13.08*	*21.04*	*9.18*	*4.69*	*8.06*
EBIT Margin (%)	*0.98*	*1.32*	*1.15*	*0.96*	*0.99*	*1.12*	*1.61*	*1.53*	*1.40*	*1.25*	*1.17*	*1.19*
EBITDA	2.15	2.44	2.07	1.55	1.37	1.15	1.43	1.35	1.19	0.99	0.92	0.89
Growth (%)	*-11.90*	*18.05*	*33.68*	*12.63*	*18.93*	*-19.00*	*5.46*	*13.84*	*20.06*	*8.00*	*3.34*	*7.96*
EBITDA Margin (%)	*1.28*	*1.59*	*1.41*	*1.14*	*1.15*	*1.31*	*1.79*	*1.69*	*1.52*	*1.38*	*1.30*	*1.34*
Net Income	1.66	0.36	1.43	-0.13	0.28	0.49	0.71	0.71	0.64	0.51	0.47	0.49
Growth (%)	*355.00*	*-74.47*	*-*	*-147.49*	*-42.44*	*-30.32*	*0.22*	*10.97*	*24.40*	*9.12*	*-5.00*	*5.50*
Net Margin (%)	*0.99*	*0.24*	*0.97*	*-0.10*	*0.24*	*0.56*	*0.89*	*0.88*	*0.82*	*0.71*	*0.67*	*0.75*

All figures in billions of U.S. Dollar.